EPA Registration No. 11556-131 Vol. 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MAY 2 4 2012

Douglas A. Spilker, Ph.D. Bayer HealthCare LLC Animal Health P.O. Box 390 Shawnee Mission, KS 66201

Subject:

Amendment - Confidential Statements of Formula (CSFs)

EPA Reg. No. 11556-131

CyLence® Ultra Insecticide Cattle Ear Tag

Your submission dated February 13, 2012

Dear Dr. Spilker:

We have no objection to the use of the revised basic and the two (2) alternate formulations CSFs (all dated 01/16/12), as requested in your letter of the above date. The revised basic CSF supersedes the current basic CSF (dated 9/8/05). The revised alternate No. 1 CSF supersedes Alt. No.1 CSF (dated 4/3/07). The amendment has been inserted in the file for the subject product. A copy of the Product Chemistry Review Memorandum is enclosed for your records.

If you have any questions regarding this action, please contact Olga Odiott at (703)308-9369.

Mark Suarez

Sincerelly

Product Manager 13

Insecticide Branch

Registration Division (7505P)

Enclosure





Re: CyLence Ultra Insecticide Cattle Ear Tag (11556-131)

Doug Spilker to: Olga Odiott

05/14/2012 01:50 PM

History:

This message has been forwarded.

flow called registrat Thanks for your reply. It was a minor formulation change that Dr. Mathur said could be a notification. Please let me know if you need an additional copy of anything.

Douglas A. Spilker, Ph.D. - Mgr., EPA Reg. Affairs Bayer HealthCare, Animal Health Division

This message may be short because it's from my Blackberry!

From: Olga Odiott [mailto:Odiott.Olga@epamail.epa.gov]

Sent: Monday, May 14, 2012 12:44 PM

To: Doug Spilker

Cc: Mark Suarez <Suarez.Mark@epamail.epa.gov>; Shyam Mathur <Mathur.Shyam@epamail.epa.gov>

Subject: Re: CyLence Ultra Insecticide Cattle Ear Tag (11556-131)

Hi Doug,

The CSFs have not been approved yet, but we did not realize there was a formulation change. Mark and I are looking into your inquiry and Mark will call you later.

Regards, Olga

Olga Odiott, Senior Biologist Registration Division Office of Pesticide Programs U.S. Environmental Protection Agency (703) 308-9369 (703) 305-6596 (fax) odiott.olga@epa.gov

Doug Spilker ---05/14/2012 08:33:14 AM---Dear Ms. Odiott, This email is in addition to the voicemail I left this morning.

From: Doug Spilker <doug.spilker@bayer.com>
To: Olga Odiott/DC/USEPA/US@EPA

Cc: Mark Suarez/DC/USEPA/US@EPA, Shyam Mathur/DC/USEPA/US@EPA

Date: 05/14/2012 08:33 AM

Subject: CyLence Ultra Insecticide Cattle Ear Tag (11556-131)

Dear Ms. Odiott,

Inert ingredient information may be entitled to confidential treatment



ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DATE: May 9, 2012

DP BARCODE No.: 400671

File Symbol No.: 11556-131

ACTION CODE: 345

DECISION No.: 462363

COMPANY: BAYER HEALTHCARE LLC

PRODUCT NAME: "CYLENCE® ULTRA INSECTICIDE CATTLE EAR TAG"

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP[| EP |X]

PC Codes: 118831; 067501

FROM:

William Herald, Microbiologist (MS) / Chemist,
Product Chemistry Team
Technical Review Branch/RD (7505P)
Regina Foushee-Smith / Mark Suarez, RM 13
Insecticide Branch / RD (7505P)

TO:

INTORDUCTION:

Registrant, BAYER HEALTHCARE LLC has submitted an amended Basic and Alt. Nos. 1 and 2 CSF formulations (all dated 1/16/12) to support the registration of the end use product, "CYLENCE® ULTRA INSECTICIDE CATTLE EAR TAG". Said proposed Basic CSF has changed the name and address of the Producer in Box 2; Box 11 the alternate supplier was removed from the Basic CSF in compliance with the Agency's sanction against reciting alternate suppliers or ingredients in a Basic CSF. Moreover, the changes that were made are all recited in Registrant's "ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE AMENDEMENT" pages 1-3. Alt. No. 1 (dated 1/16/12) supersedes the current Alt. No. 1 (dated 4/3/07) with the proposed changes and a list of producers recited on page 3 of the said attachment. Alt. No. 2 has been added to incorporate an additional inert ingredient and the proposed changes for Alt. No. 2 are recited on page 2 or the said attachment. TBR has been asked to evaluate the said proposed Basic and Alt No. 1 CSF formulations and determine their acceptability.

SUMMARY OF FINDINGS

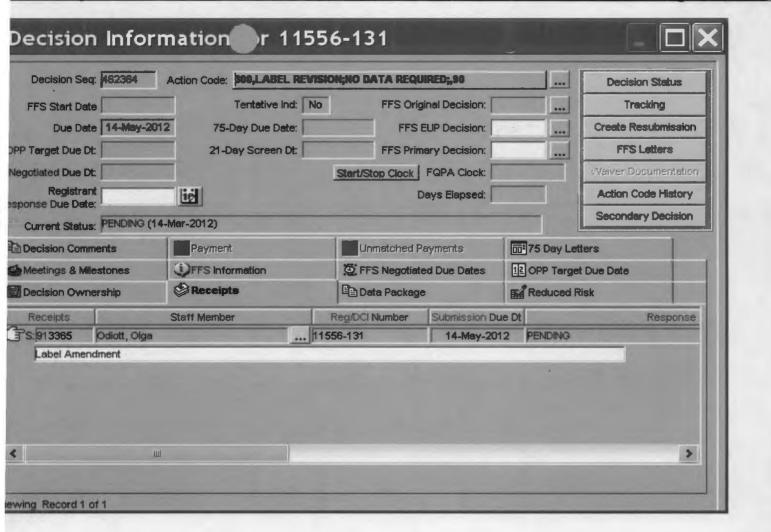
The proposed Basic and Alt Nos. 1 and 2 CSF formulations (all dated 1/16/12) contain

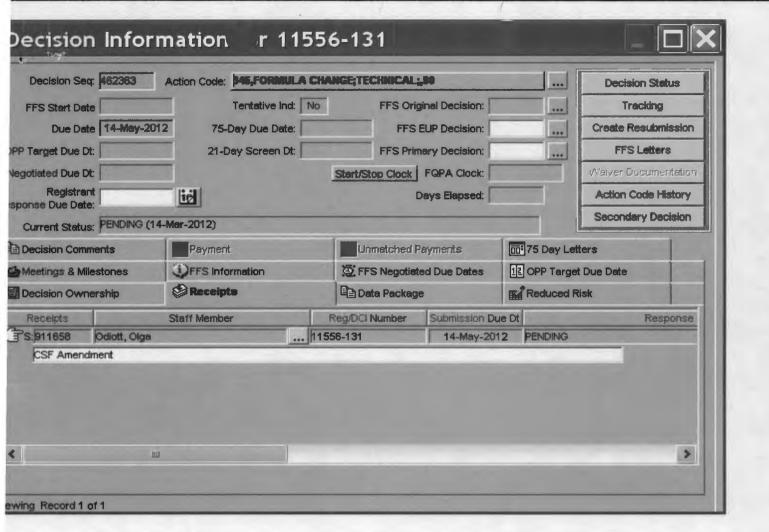
as the active ingredients with the product label claims of 8% and 20% respectively.

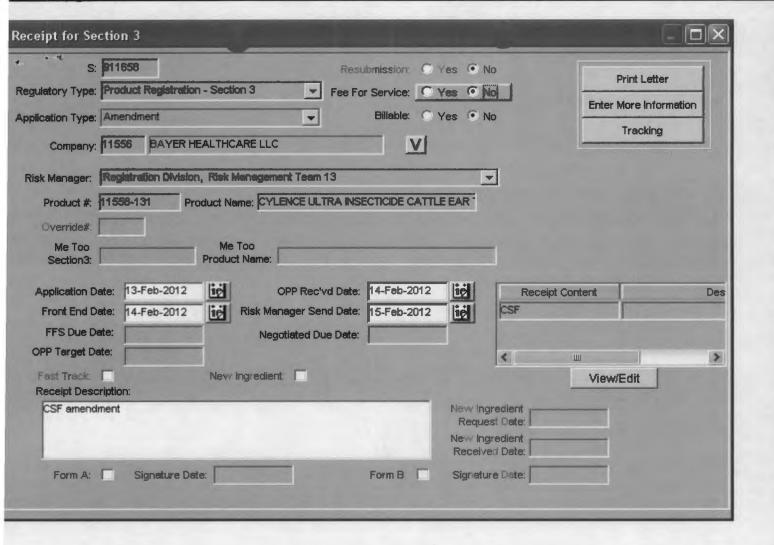
- The said proposed Basic and Alt Nos. 1 and 2 CSF formulations are in compliance with PR Notice 91-2 and Title 40 CFR § 152.43. All of the inert ingredients present in the formulation have been approved for application to animals under 40 CFR 180.930 by the Agency (A. Debesai 3/5/12).
- The upper and lower limits of the active and inert ingredients are in compliance with the statutory parameters recited in Title 40 CFR § 158.350 (b) (2).
- The nominal concentration of the active ingredient recited in the said proposed Basic and Alt Nos. 1 and 2 CSF formulations concurs with the product label claim of nominal concentration.
- The proposed said proposed Alt Nos. 1 and 2 CSF formulations are substantially similar in chemical composition and physical-chemical properties with the said proposed Basic CSF.

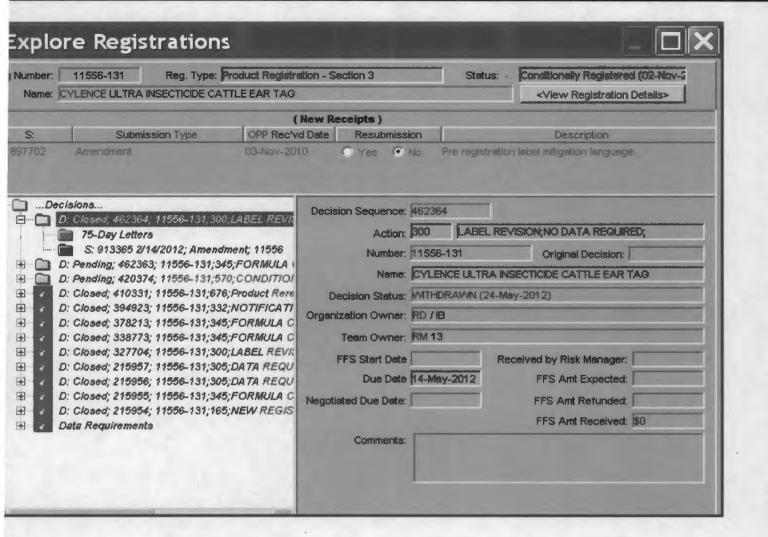
CONCLUSIONS:

- The TRB has reviewed the said proposed Basic and Alt Nos. 1-2 CSF formulations (all dated 1/16/11) and has determined them to be acceptable.
- The proposed Basic CSF (dated 1/16/12) supersede the current Basic CSF (dated 9/8/05). 2.
- The proposed Alt. No 1 CSF (dated 1/16/12) supersedes the current Alt. No. 1 CSF (dated 3/4/07).













UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

February 15, 2012

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DR. BRUCE MARTIN
BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION
PO Box 390
SHAWNEE MISSION, KS 66201-0390

PRODUCT NAME: CYLENCE ULTRA INSECTICIDE CATTLE EAR TAG

COMPANY NAME: BAYER HEALTHCARE LLC

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 11556-131 EPA RECEIPT DATE: 02/14/12

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 13, at (703) 305-0120.

Sincerely,

F. L. Answe Front End Processing Staff Information Services Branch Information Technology & Resources Management Division

Fee for Service {911658C~

This package includes the following	for Division				
New RegistrationAmendment	○ AD ○ BPPD ○ RD				
□ Studies? □ Fee Waiver? □ volpay % Reduction:	Risk Mgr. 13				
Receipt No. S. EPA File Symbol/Reg. No. Pin-Punch Date:	- 911658 11556-131 2/14/2012				
This item is NOT subject to FFS action.					
Action Code: Requested: Granted: Amount Due: \$	Parent/Child Decisions:				
Inert Cleared for Intended Use Reviewer:	Uncleared Inert in Product Date: 2/15/12				

FAST-TRACK AMENDMENTS Completed less Screening Checklist Experts In-Processing Signature (A) (1) (1) (1)

	EPA	Reg. Number: [556-13] EPA Receipt Date: 2	14	12		
77	÷ .	Chevie List Item			No	ŊA
	1	Application Form (EPA Form 8570-1) -signed?	L			
	2	Confidential Statement of Formula (EPA Form 8570-29) - signed?				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) signed?					
4	1	Formulator's Exemption Statement (EPA Form 8570-27) - signed?	1			
5	1	Data Matrix (EPA Form 8570-35) [Applicable, for adding me-too uses] a) Selective Method?				
		b) Cite-All Method? Applicant owns data or list only the companies offered to pay.				
	-	c) Public copy of Matrix provided? See PR Notice 98-5				
6	Is	Label Included? (5 copies)	V		,	
	Co	Mineral Dela Monto Clearaine -	÷			
٠	, V	Photograph Food			. ,	
		Inerts approved for the intended use. A Debeson 3/5/12				

Bayer HealthCare Animal Health



Via Federal Express

February 13, 2012

Document Processing Desk (AMEND) – Non-PRIA Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attention:

Mr. Mark Suarez, PM 13

Subject:

CyLence Ultra Insecticide Cattle Ear Tag

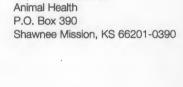
EPA Reg. No. 11556-131

Dear Mr. Suarez:

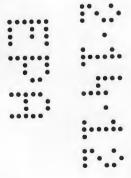
Please find enclosed for the Agency's review and acceptance minor revisions to the Basic, and two Alternate Confidential Statements of Formula, as well as revised draft labeling, dated 02/10/12, for the subject product. One copy of the draft label has been highlighted to show the minor revisions.

Briefly, the proposed changes are as follows, but more details can be found in the attachment to the application (Form 8570-1):

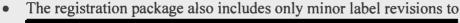
- Minor revisions to Basic and Alternate Confidential Statements of Formula to especially revise to meet the new Agency format on proper way to show optional suppliers of ingredients and optional producers.
- A second alternate formula (Alternate Formulation 2) is proposed, which incorporates the inert ingredient with a respective lowering of another inert ingredient in the formula. This was determined to qualify as an alternate formula (see attached email S. Mathur to D. Spilker, dated 10/26/11) without the need for submission of any additional data. See attachment for details.



Bayer HealthCare LLC



Bayer Healt' LLC Februar 2012 Page 2 of 2





We are hopeful, that since these are minor formula changes with no data to review, and that the label revisions are minor in nature, that these actions can be accepted expeditiously.

If you have any questions, please contact me at (913-268-2751) or doug.spilker@bayer.com.

Sincerely

Douglas A. Spilker. Ph. D.

Manager, EPA Regulatory Affairs

Doug.Spilker@Bayer.com

Enclosures:

- 1) Application for Pesticide (Form 8570-1) w/attachment
- 2) Draft Label, dated 02/10/12 (3 copies)
- 3) Draft Label, dated 02/10/12 (Highlighted; 1 copy)

Suarez 021312.doc



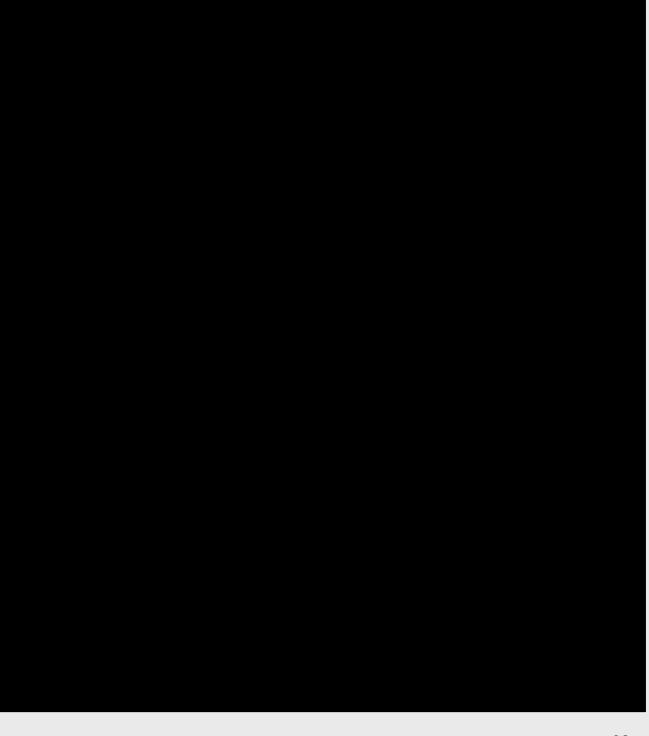
*Inert ingredient information may be entitled to confidential treat
on may be enti
dient information may be entitled to confidential trea
tial treatment*

ease read instructions on rever	se before compieung form.			For	n Approved, OMB No. 2070-0060
⇔ EPA	United States Environmental Protectio Washington, DC 204	•	☐ Registr ☑ Amend ☐ Other:		OPP Identifier Number
	Application	on for Pes	ticide - Sectior	n I	
1. Company/Product Number 11556-131	· · ·			3. Proposed Classification	
4. Company/Product (Name) CyLence Ultra Insecticide	o Cattle Far Tag	PM# 13			None Restricted
5. Name and Address of Appl Bayer HealthCare LLC PO Box 390 Shawnee Mission, KS	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No				
Check if this is a	new address	Product	Name		
		Section	n - II		
Amendment – Explain below. Resubmission in response to Agency letter dated					
		Section	ı - III		
Material This Product Will Child-Resistant Packaging	Be Packaged In: Unit Packaging		Water Soluble Pack	raging	2. Type of Container
Yes*	Yes		Yes	(aging	Metal
No	☐ No		☐ No		Plastic
*Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	Glass Paper Other (Specifiy)
		detail Containe	r	On Label	abel Directions g accompanying product
6. Manner in Which Label is Affixed to Product					
Section - IV					
1. Contact Point (Complete it	ems directly below for identification	of individual to	be contacted, if nec	essary, to process	his application)
Name Douglas A. Spilker, Ph.D	. Title		ager, EPA Reg. Aff	• •	elephone No. (Include Area Code) 913-268-2751
acknowledge that any knowir under applicable law.	Certification have made on this form and all attention ngly false or misleading statement in	nchments there			6. Date Application Received (Stamped)
2. Signature	1. Spiller 3	. Title Ma	nager, EPA Reg. A	ffairs	•••••
4. Typed Name Douglas A. Spilker (do	Date	Fe6 2012	2	••••	

ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE AMENDMENT Page 1 of 3

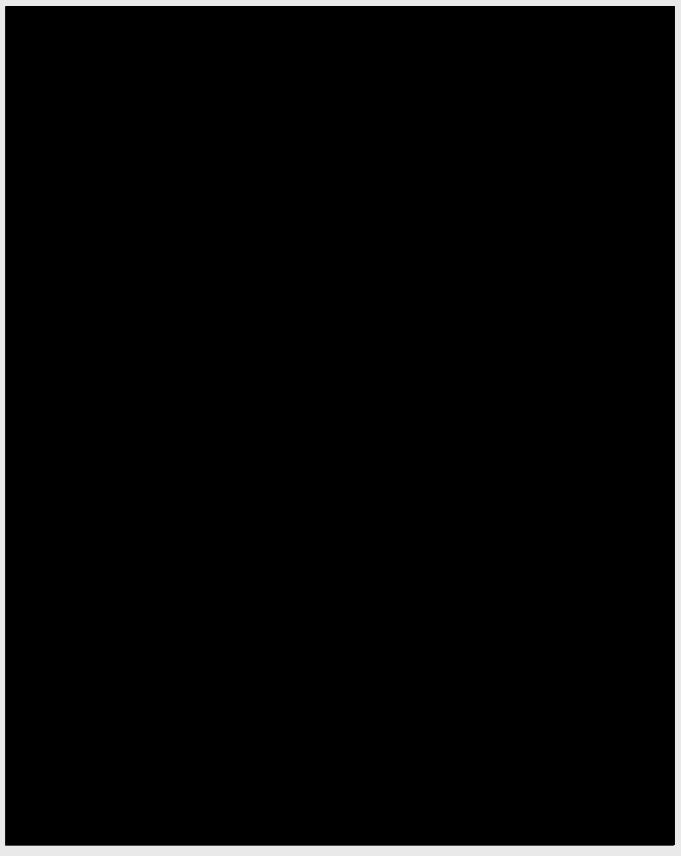
CyLence Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131

A. Enclosed for Agency acceptance are two (2) copies of the revised **Basic Confidential Statement of Formula**, dated January 16, 2012 for CyLence Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131, which supersedes the current Basic CSF on file with the Agency, dated September 8, 2005 (attached). The proposed changes for the Basic formulation are described below:



ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE AMENDMENT Page 2 of 3

CyLence Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131



ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE AMENDMENT Page 3 of 3

CyLence Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131



Doug Spilker

From:

Mathur.Shyam@epamail.epa.gov

Sent:

Wednesday, October 26, 2011 7:30 AM

To:

Doug Spilker

Subject:

Re: FW: CyLence Ultra Cattle Ear Tag - Request for Guidance (Any Update?)

Good Morning Doug: I think it looks ok as alternate CSF. You can submit Minor Formulation Amendment via notification process. Have a very nice day.

shyam

Shyam Mathur, Ph.D Product Chemistry Team Leader Technical Review Branch/Registration Division OPP / USEPA 703-308-9374

From:

Doug Spilker < doug.spilker@bayer.com >

To:

"Mathur.Shyam@epamail.epa.gov'"

< <u>IAI 9</u>

<<u>Mathur.Shyam@epamail.epa.gov'</u>>

Cc:

Wally Li <<u>wally.li@bayer.com</u>> 10/25/2011 03:57 PM

Date:

Subject: FW: CyLence Ultra Cattle Ear Tag - Request for Guidance (Any

Update?)

Hi Dr. Mathur,

Is there any update regarding this question?

Thank you and, Best Regards,

Doug

Douglas A. Spilker, Ph.D.

Manager - EPA Reg. Affairs BAYER HEALTHCARE LLC

Animal Health Division

Office: 913-268-2751 Mobile: 816-506-3102

Email: doug.spilker@bayer.com

Address:

P.O. Box 390

Shawnee Mission, KS 66201-0390

Country: USA

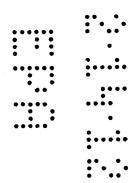
Bayer Animal Health "Protecting.Curing.Caring...Together"

----Original Message----

From: Doug Spilker

Sent: Thursday, October 13, 2011 12:05 PM To: 'Mathur.Shyam@epamail.epa.gov'

Subject: RE: CyLence Ultra Cattle Ear Tag - Request for Guidance



Dr. Mathur, Thank you for the update.

Best Regards, Doug

Douglas A. Spilker, Ph.D. Manager - EPA Reg. Affairs BAYER HEALTHCARE LLC Animal Health Division Office: 913-268-2751

Mobile: 816-506-3102

Email: doug.spilker@bayer.com

Address: P.O. Box 390 Shawnee Mission, KS 66201-0390 Country: USA

Bayer Animal Health "Protecting.Curing.Caring...Together"

----Original Message----

From: Mathur.Shyam@epamail.epa.gov [mailto:Mathur.Shyam@epamail.epa.gov]

Sent: Thursday, October 13, 2011 11:58 AM

To: Doug Spilker

Subject: Re: CyLence Ultra Cattle Ear Tag - Request for Guidance

Good afternoon Mr. Spilker: I will discuss this issue with other colleagues and let you know.

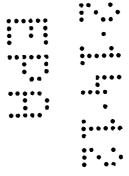
shyam Shyam Mathur, Ph.D Product Chemistry Team Leader Technical Review Branch/Registration Division OPP / USEPA 703-308-9374

From: Doug Spilker < doug.spilker@bayer.com > To: Shyam Mathur/DC/USEPA/US@EPA Cc: Richard Gebken/DC/USEPA/US@EPA

Date: 10/12/2011 04:27 PM

Subject: CyLence Ultra Cattle Ear Tag - Request for Guidance

(Embedded image moved to file: pic12455.gif)
Dear Dr. Mathur,
We were hoping that you could give us some preliminary guidance regarding a proposal for the re-formulation of one of our cattle ear tags. We are in a little bit of a predicament regarding one of our ear tags, as it contains



Another proposal is to improve a previous formulation, CyLence Ultra Insecticide Cattle Ear Tag (EPA Reg. No. 11556-131) by replacing part of Please see

attached our proposed CSF.

The proposed formulation

will have no change in % active ingredient. We feel that this minor substitution of an approved inert ingredient would allow it to be an alternate formulation of the current product, and therefore not require new acute toxicity data or additional product chemistry data. It should also qualify for fast-track review.

After your review of the proposed CSF with please let us know if our determination is correct that this could be considered as an alternate formulation of the current CyLence Ultra Cattle Ear Tag registration, and that no additional data would be needed?

Thank you for your assistance, and best regards, Doug

Douglas A. Spilker, Ph.D. Manager - EPA Reg. Affairs BAYER HEALTHCARE LLC Animal Health Division Office: 913-268-2751 Mobile: 816-506-3102

Email: doug.spilker@bayer.com

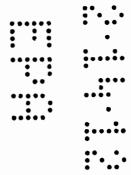
Address: P.O. Box 390 Shawnee Mission, KS 66201-0390 Country: USA

Bayer Animal Health "Protecting.Curing.Caring...Together"

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For alternate languages please go to http://bayerdisclaimer.bayerweb.com

[attachment "CyLence Ultra CET Proposed CSF Bayer.pdf" deleted by Shyam Mathur/DC/USEPA/US]







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 22, 2011

Douglas A. Spilker, Ph. D. Bayer Health Care LLC Animal Health P.O Box 390 Shawnee Mission, KS 66201-0390

Subject:

Amended Reregistration Label

Prooduct Name: Cylence Ultra Insecticide Cattle Ear Tag

EPA Registration No. 11556-131 EPA Decision Number: 450422

Dear Dr. Spilker:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the referenced product in connection with the **Piperonyl Butoxide RED**, and has concluded that your submission is acceptable.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated March 8, 2002

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

PLEASE NOTE: This product is <u>not</u> being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

A copy of your label stamped "Accepted" is enclosed. If you have any questions about this letter, please contact Driss Benmhend at (703) 308-9525 or via e-mail at Benmhend.driss@epa.gov

Sincerely Yours,

Richard J. Gebken Product Manager (10)

Insecticide Branch

Registration Division (7504P)

Enclosures: Label stamped "Accepted with Comments"

000121-00034 D400841

Label Modifications according to PBO

RED

Date:

07/27/2011

Supersedes:

05/28/2008

Page 1 of 7

Pouch

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks for Up to Five Months.

		Percent By Weight
Active Ingredients	Beta-cyfluthrin	8%
	Piperonyl butoxide	20%
Other Ingredients		72%
Total		100%

Keep Out of Reach of Children

CAUTION

See Box For Precautionary Statements

Net Contents: 10 Tags - 0.5 oz per tag

Manufactured for
Bayer HealthCare, Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201 U.S.A.

ACCEPTED AUG 2 2 2011 Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:

EPA. Reg. No: 11556-131

EPA Est. No. XXX-XX-X •••• EPA Reg. No. 11556-131 •••••

Laber Modifications according to PBO

RED

Dare:

07/27/2011

Supersedes: Page 2 of 7 05/28/2008

Box (Front)

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For Use with Allflex Universal Total Tagger with red pin and black clip.

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks

- Effective Against Face Flies and Pyrethroid Susceptible Horn Flies for up to 5 months.
- Kills and Repels Face Flies mechanical vector of *Moraxella bovis* bacteria causing "pink eye" of cattle
- Synergized for extra performance

		Percent By Weight
Active Ingredients	Beta-cyfluthrin	8%
	Piperonyl Butoxide Technical	20%
Other Ingredients		72%
Total		100%

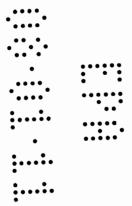
Keep Out of Reach of Children

CAUTION

See Side Panel for Additional Precautionary Statements

Net Contents: 2 pouches of 10 tags each – 0.5 oz per tag

Bayer HealthCare, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201 U.S.A.



Laber Modifications according to PBO

RED

Laie:

07/27/2011

Supersedes:

05/28/2008

Page 3 of 7

Box (Side Panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes or on clothing. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

User should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

FIRST AID

If on skin or	Take off contaminated clothing.		
clothing:	Rinse skin immediately with plenty of water for 15-20 minutes.		
	Call a poison control center or doctor for treatment advice.		
If in Eyes:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye. Call a poison control center or doctor for treatment advice. 		
If Swallowed:	 Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person. 		



Laber Modifications according to PBO

RED

Late:

07/27/2011

Supersedes:

05/28/2008

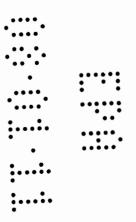
Page 4 of 7

If Inhaled:

- Move person to fresh air.
- If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment, call 1-800-422-9874. For customer service or to obtain product information, including MSDS, call 1-800-633-3796.

Environmental Hazards: This product is toxic to aquatic organisms, including fish and aquatic invertebrates. Do not contaminate water when disposing of used tags. Apply this product only as specified on the label.



Laber Modifications according to PBO

RED

Laie:

07/27/2011

Supersedes:

05/28/2008

Page 5 of 7

Box (Back)

Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating).

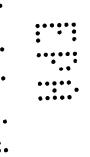
All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. CyLence® Ultra Insecticide Ear Tags have been proven to be effective against face and horn flies for up to five months.

Use the Allflex Universal Total Tagger with the red pin and black clip to apply tags to cattle.

Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

(Illustration)	(Illustration)	(Illustration)	(Illustration)
Figure 1	Figure 2	Figure 3	Figure 4
Disinfect pliers prior to use. Place male button onto pin until it projects through the tip.	Slide tag under the clip of the pliers by depressing the lever.	Position tag in the center portion of the front side of the ear.	Apply the tag between the second and third rib cartilage.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. CyLence® Ultra Cattle Ear Tag contains the pyrethroid insecticide beta-cyfluthrin plus piperonyl butoxide, which is an insecticide synergist.



Laber Modifications according to PBO

RED

Late:

07/27/2011

Supersedes:

05/28/2008

Page 6 of 7

Box (Back)

Storage and Disposal:

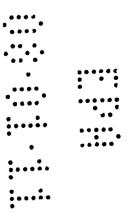
Do not contaminate water, food or feed by storage or disposal.

Storage: Store in cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned stay out of smoke.

EPA Est. No. XXX-XX-X EPA Reg. No. 11556-131



Laber Modifications according to PBO

RED

Daie:

07/27/2011

Supersedes:

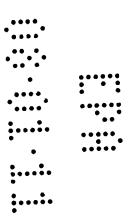
05/28/2008

Page 7 of 7

Box (Side Panel)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.



Bayer HealthCare Animal Health



Via Federal Express 07/29/2011

Document Processing Desk (AMEND) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Enclosure:

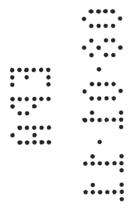
Application for Pesticide Label Amendment - Non-PRIA Action

Bayer HealthCare LLC Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390

CyLence Ultra Insecticide Cattle Ear Tag (EPA Reg. No. 11556-131); formerly "Cutter Ultra Insecticide Cattle Ear Tag"

- 1. Attachment for Application for Pesticide Label Amendment
- 2. Revised label (5 copies)
- 3. Revised label highlighted (1 copy)
- 4. Copy of Notification, dated 1/7/2001, showing change in primary brand name for this product





Print Form Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-**OPP Identifier Number** Registration United States **Environmental Protection Agency Amendment** Washington, DC 20460 Other Application for Pesticide - Section I 1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification 11556-131 M. Suarez X None Restricted PM# 4. Company/Product (Name) CyLence Ultra Insecticide Cattle Ear Tag Team 13 5. Neme and Address of Applicant (Include ZIP Code) 6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) Bayer HealthCare LLC, Animal Health Division (b)(i), my product is similar or identical in composition and labeling P. O. Box 390 EPA Reg. No. Shawnee Mission, KS 66201-0390 Check if this is a new address **Product Name** Section - II Final printed labels in repsonse to Amendment - Explain below. Agency letter dated "Me Too" Application. Resubmission in response to Agency letter dated Notification - Explain below. Other - Explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.) Enclosed for Agency acceptance are revised draft labeling, dated 07/27/2011, revised as requested pursuant to the PBO RED. Please see attached for further information. Non-PRIA action. Section - III 1. Material This Product Will Be Packaged In: Child-Resistant Packaging Unit Packaging Water Soluble Packaging 2. Type of Container Metal Yes Yes Plastic Text No No Glass Paper If "Yes" If "Yes" No. per container No. per * Certification must Unit Packaging wgt. container Package wgt Other (Specify) be submitted 3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions On Label On Labeling accompaning product Container 6. Manner in Which Label is Affixed to Product Other Lithograph Paper glued Stanciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Title Telephone No. (Include Area Code) Douglas A. Spilker, Ph. D. (doug.spilker@bayer.com) Manager, EPA Regulatory Affairs 913-268-2751 6. Date Applications Certification I certify that the statements I have made on this form end all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or (Stampad) both under applicable law. 2. Signature 3. Title to A. fille Manager, EPA Regulatory Affairs 4. Typed Name 5. Date 29 July 2011 Douglas A. Spilker, Ph. D. 56

ATTACHMENT FOR APPLICATION FOR PESTICIDE REGISTRATION July 29, 2011

Bayer HealthCare LLC, Animal Health Division

CyLence Ultra Insecticide Cattle Ear Tag (EPA Reg. No. 11556-131)

The following revisions have been made to the enclosed draft label as requested by the Agency in an email and pursuant to the requirements of the Piperonyl Butoxide RED (Driss Benmhend to Doug Spilker, dated 07/27/2011; see attached). Please also find attached a highlighted version showing these changes:

- Revision of the Hazards to Humans and Domestic Animals section; email item No. 2 (label page 3).
- 2. Addition of the **User Safety Requirements**; "Follow manufacturer's..."; email item No. 3 (label page 3).
- 3. Addition of the **User Safety Recommendations** section; email item No. 4 (label page 3).
- 4. Reordering of the toxicity rankings in the **First Aid** statements; email item No. 1 (label pages 3 and 4).
- 5. Revision of the **Environmental Hazards** statements; email item No. 5 (label page 4).
- 6. Removal of a specific production establishment number in two places; we are uncertain at this time where this product would be made (label pages 1 and 6).

Please note, the primary brand name for this product was changed via Notification; • dated 1/7/2001 (see attached).





Oriss Benmhend <Benmhend.Driss@epamail.e pa.gov>

07/27/2011 08:23 AM

To Doug.Spilker@Bayer.com

cc Linda Arrington < Arrington.Linda@epamail.epa.gov>

bcc

Subject Product Cutter Ultra Insecticide Cattle Ear Tag (Reg Number: 11556-131)

Dear Mr. Spilker:

I just completed the review of the information submitted to support your application for the re-registration of the product Cutter Ultra Insecticide Cattle Ear Tag (Reg Number: 11556-131). Based on our review, the product label must revised to incorporate all the mandatory mitigation language required by the REDs. I have listed the required revision in the attached document. Please go through the revisions and submit an updated label that incorporates all mandatory mitigation language required.

(See attached file: Re-reg. 11556-131.Review.doc)

Please let me know if you have questions regarding this action Thanks
Regards





(Embedded image moved to file: pic24515.gif) Re-reg. 11556-131. Review.doc pic24515.gif

Date: July 27, 2011

Reg. No.: 11556-131

Product Name: Cutter Ultra Insecticide Cattle Ear

Active Ingredient(s) Assessed: Piperonyl butoxide/067501

1) Based on toxicity ranking per the acute toxicity review, the First Aid statements should be placed on the label in the following order:

"IF ON SKIN OR CLOTHING:...

IF IN EYES:...

IF SWALLOWED:...

IF INHALED:..."

2) Per the acute toxicity review, the Hazards to Humans and Domestic Animals must be revised to read:

"CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes or on clothing. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material."

3) Per the RED, the following User Safety Requirements text must be added to the label:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."

4) Per the RED, the following User Safety Recommendations must be added to the label and placed in a box:

"User Safety Recommendations

User should wash hands before, eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. As soon aspossible, wash thoroughly and change into clean clothing."

5) The first sentence of the Environmental Hazards statements must be revised to read:

"This product is toxic to aquatic organisms, including fish and aquatic invertebrates."

PEPA	Un Environmental	ited States	gency	v	Registre Amendi Other	ation	OPP Identifier Number
		Application fo	r Pesticio	le - Section	1		
Company/Product Number			2. EPA F	roduct Manager		3. Pr	roposed Classification
Company/Orandon (Al-	11556-131		Dage	George Lai	Rocca	-	None Restricted
Company/Product (Name CyLe	nce Ultra Cattle Inse	cticide Ear Tag	PM#				
Name and Address of Apayer Corporation, A.O. Box 390 nawnee Mission, K.	nimal Health, Agri		(b)(i), m to: EPA R		nilar or ident	tical in co	FIFRA Section 3(c)(3) omposition and labeling
		S	ection - I				
Amendment - Explair Resubmission in res	ponse to Agency letter (detod	_ <u>_</u> _	Final printed labor Agency latter da "Me Too" Applic Other - Explain b	eted pation.	a to	•
D	attached explanation.	Se	ection - II	1		-	
Material This Product Wi	il Be Packaged in:						
d-Resistent Peckeging Yes No	Unit Packaging Yes No	E	Yes No		2. Type of	Metal Plastic Glass Paper	
Partification must submitted	If "Yes" Unit Peckaging wgt.		'Yes" ckage wgt	No. per container			Specify)
cation of Net Contents	Information Container	4. Size(e) Retail Co	nteiner	5. L	On Label a	bel Directi	
lanner in Which Lebel is	Affixed to Product	Lithograph Paper glued Stenciled		Other			
		Se	ection - I	V			••••
ontact Point Complete	items directly below for	or identification of in	ndividual to b	contacted, if ne	cessary, to p	rocess this	s application.)
F. Terry McNama	ara	Title Direc	ctor, Preclin	Dev. and EPA R	eg. Affairs	Telephor (913) 26	ne No. (ipciyde Area Code) 8-2588
	ements I have made on ny knowlinglly false or r I law.						6. Date Application Received (Stamped)
	Mc Ham		ctor, Preclinica	l Development and	d EPA Reg. Af	fairs	-
F. Terry McNamar		5. Dat		January 7, 2001			•

APPLICATION FOR PESTICIDE

Notification of Product Name Change per PR Notice 95-2.

Bayer Corporation, Animal Health is changing the name of its product Cutter Ultra Insecticide Cattle Ear Tag (EPA Reg. No. 11556-131) to CyLence[®] Ultra Insecticide Cattle Ear Tag.

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for this product. Bayer understands that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. Bayer further understands that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CRF 152.46, this product may be in violation of FIFRA and Bayer may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.





Product Cutter Ultra Insecticide Cattle Ear Tag (Reg Number: 11556-131)

Driss Benmhend to: Doug.Spilker

07/27/2011 09:23 AM

Cc: Linda Arrington

Dear Mr. Spilker:

I just completed the review of the information submitted to support your application for the re-registration of the product Cutter Ultra Insecticide Cattle Ear Tag (Reg Number: 11556-131). Based on our review, the product label must revised to incorporate all the mandatory mitigation language required by the REDs. I have listed the required revision in the attached document. Please go through the revisions and submit an updated label that incorporates all mandatory mitigation language required.



Re-reg. 11556-131. Review.doc

Please let me know if you have questions regarding this action Thanks
Regards



Driss Benmhend, Biologist Registration Division Phone: (703) 308-9525, Fax (703) 308-0029

Mailing Address:
U.S. EPA-OPP
Registration division, Mail
Code: (7505P)
1200 Pennsylvania Avenue,
NW
Washington DC, 20460

62

Date: July 27, 2011

Reg. No.: 11556-131

Product Name: Cutter Ultra Insecticide Cattle Ear

Active Ingredient(s) Assessed: Piperonyl butoxide/067501

1) Based on toxicity ranking per the acute toxicity review, the First Aid statements should be placed on the label in the following order:

"IF ON SKIN OR CLOTHING:...

IF IN EYES:...

IF SWALLOWED:...

IF INHALED:..."

2) Per the acute toxicity review, the Hazards to Humans and Domestic Animals must be revised to read:

"CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes or on clothing. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material."

3) Per the RED, the following User Safety Requirements text must be added to the label:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."

4) Per the RED, the following User Safety Recommendations must be added to the label and placed in a box:

"User Safety Recommendations

User should wash hands before, eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."

5) The first sentence of the Environmental Hazards statements must be revised to read:

"This product is toxic to aquatic organisms, including fish and aquatic invertebrates."

Material to be added to an e-Jacket/Jacket

Reg. No. 11556-131
Description: Product Reregistration (180)
1. □ Placement within the e-Jacket/jacket: □ Default: (chronological, top = newest) □ File Location: (PDF page number, i.e., "before page 45")
2. Send to Data Extraction contractors this material: Newly stamped accepted label Notification New CSF Other: 3. Attach this coversheet to the top of the material or jacket. It must be
well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).
Reviewer's Name:Stokes
Phone: Division:PRD
Date:

This form was created on 8/24/2009

DATA PACKAGE BEAN SHEET

Date: 23-Nov-2010 Page 1 of 1

Decision #: 410331

DP #: (384303)

NON PRIA

Parent DP #:

Submission #: 867327

* * * Registration Information * * *

Registration:	11556-131 - CUTTER	ULTRA IN	ISECTICID	E CATTL	E EAR TAG		
Company:	11556 - BAYER HEALTHCA	RE LLC					
Risk Manager:	RM 13 - Mark Suarez - (703) 305-0120 Room# PY1 S-7246						
sk Manager Reviewer:	Julia Stokes JSTOKES4						
Sent Date:	18-Feb-2010	Calculat	ed Due Date:	16-Feb-201	0	Edited Due Date:	
Type of Registration:	Product Registration - Section	on 3					
Action Desc:	(676) Product Reregistration	Decision;					
Ingredients:	067501, Piperonyl butoxide(20%)					
	118831, beta-Cyfluthrin(8%)						
	* * * D	ata Pacl	kage Info	rmation	า * * *		
Expedite:	○ Yes ● No		Date Sent:	23-Nov-201	10	Due Back:	
DP Ingredient:	067501, Piperonyl butoxide						
	118831, beta-Cyfluthrin						
DP Title:	PBO product 11556-131 for	FINAL REVI	EW in RD				
CSF Included:	Yes No Lab	el Included:	● Yes ○	No P	arent DP #:		
Assigned To	<u> </u>	Date	<u>In</u>	Date Out	<u>. </u>		
Organization: RD / IE	3				Last Possible	Science Due Date:	
Team Name: RM 13						Science Due Date:	
Reviewer Name:					Sub Data	Package Due Date:	
contractor Name:			-				
	* * * Stu	dies Ser	nt for Re	view * *	*		
		No St	udies				
	* * * Additional D	ata Paci	cage for	this Dec	ision * * *		

Can be printed on its own page

* * * Data Package Instructions * * *

Please accept this PBO product 11556-131 for final Review in RD. CAS claim opt 8 N/A on RSRR form.

Thanks Julia

65

PRODUCT REREGISTRATION SUPPORTING DOCUMENTATION

FOR .

Case Name:	1130	V
Reg. No.	11556-13	

This supporting documentation (in chronological order) includes:

- o Old labels (identified as "Superceded by label dated xx/xx/xx)
- o Unacceptable CSF (marked "Not acceptable" and dated)
- Q Product chemistry reviews
- Acute toxicity reviews
- o Efficacy and or special studies (if necessary)
- 90-Day responses to PDCI (forms A and B)
- Administrative forms (Application for Reregistration Certification to Data citation, Data Matrix)
- Correspondence (Company and Agency letters & e-mails)

Date: November 4, 2010

Reg. No.: 11556-131

Product Name: Cutter Ultra Insecticide Cattle Ear Tag (Name of record with the

Agency), Cylence Ultra Insecticide Cattle Ear Tag (Name on draft label)

PM Name/Number: Mark Suarez, Risk Management Team 13

Primary Reviewer: Judy Loranger (Signed/JL/11/22/10) Secondary Reviewer: Mark Perry (2nd/MP/11/22/10)

New label or date of RD amended label: New, Received on 2/16/10

Active Ingredient(s) Assessed: Piperonyl butoxide/067501

Formulation Type: Impregnated Material per OPPIN

Other ai's in product

Name/PC code: Reregistration Status or Registration Date:

Beta-Cyfluthrin/11883 Registered after 11/84.

Note to PM:

1) The Risk Management and Implementation Branch V (RMIB V) is uncertain whether the following application restriction text is appropriate for this product and defers to RD regarding this issue:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Assessment can be found N:\RMIBV\label\011556/131

1) Based on toxicity ranking per the acute toxicity review, the First Aid statements should be placed on the label in the following order:

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IF IN EYES:...

IF SWALLOWED:...

IF INHALED:..."

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3) Per the RED, the following User Safety Requirements text must be added to the label:

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Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."

5) The first sentence of the Environmental Hazards statements must be revised to read:

"This product is toxic to aquatic organisms, including fish and aquatic invertebrates."

Date: November 4, 2010

Reg. No.: 11556-131

Product Name: Cutter Ultra Insecticide Cattle Ear Tag (Name of record with the

Agency), Cylence Ultra Insecticide Cattle Ear Tag (Name on draft label)

PM Name/Number: Mark Suarez, Risk Management Team 13

Primary Reviewer: Judy Loranger

Secondary Reviewer: Mark Perry

Just rorais 11/22/10

New label or date of RD amended label: New, Received on 2/16/10

Active Ingredient(s) Assessed: Piperonyl butoxide/067501

Formulation Type: Impregnated Material per OPPIN

Other ai's in product

Name/PC code:

Reregistration Status or Registration Date:

Beta-Cyfluthrin/11883

Registered after 11/84.

Note to PM:

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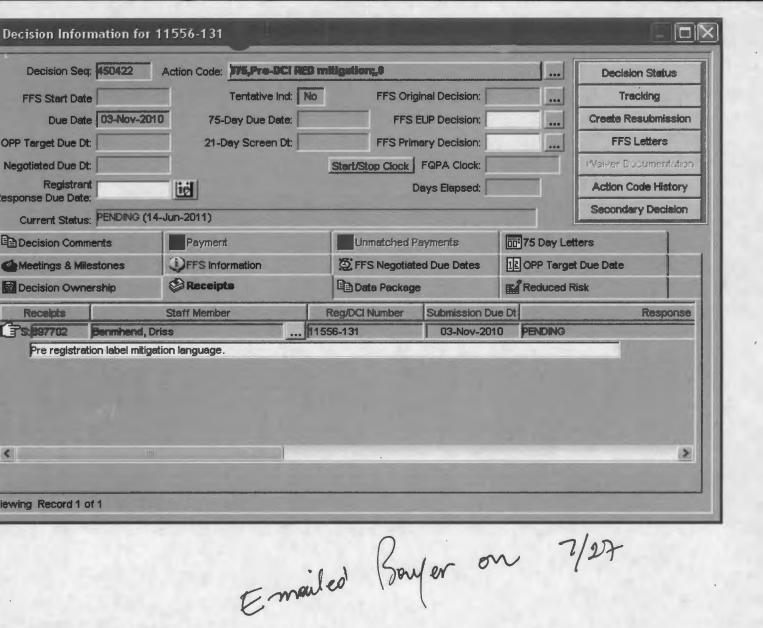
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"This product is toxic to aquatic organisms, including fish and aquatic invertebrates."



DATE OUT: 01/NOV/2010

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP []; EUP [X]

BARCODE NO.: D383452 REG./FILE SYMBOL NO.: 11556-131

PRODUCT NAME: CyLence Ultra Insecticide Cattle Ear Tag

COMPANY NAME: Bayer HealthCare, LLC ACTION CODE: 676

FROM:

Maria Rivera Piansay, Chemist

Product Chemistry Team

Risk Management and Implementation Branch V Pesticide Re-evaluation Division (7508P)

TO: Julia Stokes, CRM

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

INTRODUCTION:

In response to our review dated 9/21/10 (DP number 374684), Bayer HealthCare, LLC provided revised Confidential Statements of Formula (CSF), one basic and one alternate formulation, both dated 10/11/2010. The registrant is requesting reregistration of their product, CyLence Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131.

FINDINGS:

- 1. EPA Reg. No. 11556-131 is an end-use insecticide, containing the active ingredients, Beta Cyfluthrin and PBO, with label claim nominal concentrations of 8% and 20%, respectively. The product is an insecticide ear tag for use in controlling flies and ticks on beef and dairy cattle. The product is produced by a non-integrated system.
- 2. The registrant had corrected the CSFs as specified in Finding 2 of the previous review. The basic CSF had also been revised to show only one supplier for each active and inert ingredient and all alternate sources are now appearing in the alternate CSF. PRD/RMIB V has no objections to the acceptability of these CSFs. These CSFs (both dated 10/11/2010) should supersede previous CSFs for this product.
- 3. The Ingredients Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2 and 97-6. No data are present to trigger the need for a Physical or Chemical Hazards Statement. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3. The following revision to the label is recommended: place the Storage and Disposal Statements in a text box for prominence.

NOTE TO CRM: The labeling issues should be addressed during label review.

CONCLUSIONS:

The registrant has satisfied the product chemistry requirements for the reregistration of EPA Reg. No. 11556-131.

DATE OUT: 01/NOV/2010

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP []; EUP [X]

BARCODE NO.: D383452 REG./FILE SYMBOL NO.: 11556-131

PRODUCT NAME: CyLence Ultra Insecticide Cattle Ear Tag

COMPANY NAME: Bayer HealthCare, LLC ACTION CODE: 676

FROM:

Maria Rivera Piansay, Chemist

Product Chemistry Team

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

TO:

Julia Stokes, CRM

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

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NOTE TO CRM: The labeling issues should be addressed during label review.

CONCLUSIONS:

The registrant has satisfied the product chemistry requirements for the reregistration of EPA Reg. No. 11556-131.

Bayer HealthCare Animal Health



Via Federal Express

October 12, 2010

Document Processing Desk (DCI/SRRD)
Ms. Julia Stokes
Office of Pesticide Programs (7508P)
U.S. Environmental Protection Agency
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202

Subject: Piperonyl Butoxide Reregistration Confidential Statement of Formula for

CyLence Ultra Insecticide Cattle Ear Tag

EPA Reg No.: 11556-131

Response to Letter Dated September 30, 2010

Dear Ms. Stokes:

This is in response to the subject letter from EPA (Patricia L. Moe) dated September 30, 2010, and received on October 5, 2010, concerning the reregistration of the subject product.

As requested in the aforementioned letter, we have revised both the Basic and Alternate Confidential Statements of Formula (CSF), as described in the review by Maria Piansay, dated September 21, 2010. Two original copies of each CSF are enclosed.

If there are any questions concerning this response, please contact me by phone (913-268-2751) or email.

Sincerely

Douglas A. Spilker. Ph. D.

Manager, EPA Regulatory Affairs

Doug.Spilker@Bayer.com

Enclosures:

CyLence Ultra Insecticide Cattle Ear Tag CSF-Basic, dated 10/11/10 (2 copies) CyLence Ultra Insecticide Cattle Ear Tag CSF-Alt., dated 10/11/10 (2 copies)

OCT 14 2010

Bayer HealthCare LLC Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390

CERTIFIED MAIL. RECEIPT (Domestic Mail Only; No Insurance Coverage 244E For delivery information visit our website at www.usps.com USE EPA REG. NO. 2890 11556-131 PIPERONYL BUTOXIDE tricted Delivery Fee J. STOKES 9/29/10 7008, 2810 CARE DOUGLAS SPIKER BAYER HEALTHSTORED BOX NO. PO BOX 390 SHAWNEE MISSION, KANSAS 66201-0390 See Reverse for Instructions PS Form 3800, August 2006

	COMFLETE THIS SECTION ON DELIVERY
SENDER: COMPLETE THIS SECTION Complete Internal Planta of Also complete Internal Intern	A Signature A Signature A Addresse B. Received by (Printed Name) C. Date of Deliver C. Date of Deliver
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USEPA/OCSPP/OPP/PRD/RMIBV/MC7508P

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WASHINGTON, DC 20460

OCT 14 2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

SEP 3 1 2010

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

CERTIFIED MAIL PBO-76

Dr. Douglas A. Spilker
Bayer Healthcare LLC
Animal Health Division
PO Box 390
Shawnee Mission, Kansas 66201-0390

Subject: Piperonyl Butoxide Product Reregistration

Confidential Statement of Formula for EPA Reg. No. 11556-131

Dear Dr. Spilker:

The Confidential Statement of Formula (CSF) supporting this product has deficiencies that must be addressed. Please refer to the enclosed review for specific details:

EPA Reg. No. 11556-131, by Maria Piansay, review dated September 21, 2010:

• Finding 2: The CSFs for the basic and alternate formulations, dated 2/9/10 are not acceptable. Submit a revised basic and alternate CSF.

Please submit the required information within 10 days from the receipt of this letter. Failure to submit the information within the specified time frame will result in a Notice of Intent to Suspend your Piperonyl Butoxide product registration. Please contact Julia Stokes at (703)347-8966 if you have questions.

Sincerely,

Patricia L. Moe, Chief

Risk Management and Implementation Branch V

atricia Lhoe

Product Re-Evaluation Division

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

CERTIFIED MAIL PBO-76

Dr. Douglas A. Spilker
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Sincerely,

Patricia L. Moe, Chief Risk Management and Implementation Branch V Product Re-Evaluation Division

Enclosure

	CONCURRENCES							
7508P	75081							
STOKES	mue							
9/21/10	9/29/10							
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EPA FORM 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

DATE OUT: 21/SEP/2010

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP []; EUP [X]

BARCODE NO.: D374684 REG./FILE SYMBOL NO.: 11556-131

PRODUCT NAME: CyLence Ultra Insecticide Cattle Ear Tag

MRID NOS.: 451597-01 and 478509-01

COMPANY NAME: Bayer HealthCare, LLC

PROJECT CODE: PRD-173 OPII

ACTION CODE: 676

FROM:

Maria Rivera Piansay, Chemist learie , flies , Plansay

Product Chemistry Team

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

TO:

Julia Stokes, CRM

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

INTRODUCTION:

CONTRACTOR: CSC

A Reregistration Eligibility Decision (RED), Case number 2525, was issued on June 14, 2006 for the Technical Grade Active Ingredient (TGAI) Piperonyl Butoxide (PBO). According to the RED, the generic data base supporting the reregistration of Piperonyl Butoxide for currently registered uses has been reviewed and found to be substantially complete.

In the 8-month response to the Piperonyl Butoxide (PBO) RED, Bayer HealthCare, LLC provided a Confidential Statements of Formula (CSF), one basic and one alternate formulation, both dated 2/9/2010; EPA Form 8570-35 (Data Matrix), dated 2/8/2010; and a draft label, dated 2/10/2010; and cited product chemistry data, in MRID Nos. 451597-01 and 478509-01. The registrant is requesting reregistration of their product, CyLence Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131.

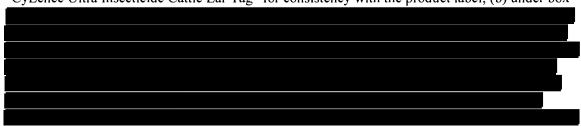
FINDINGS:

- 1. EPA Reg. No. 11556-131 is an end-use insecticide, containing the active ingredients, Beta Cyfluthrin and PBO, with label claim nominal concentrations of 8% and 20%, respectively. The product is an insecticide ear tag for use in controlling flies and ticks on beef and dairy cattle. The product is produced by a non-integrated system.
- 2. The CSFs for the basic and alternate formulation are not acceptable. The Registration Division (RD) and the Pesticide Re-evaluation Division (PRD) are no longer allowing alternate sources of active ingredients and inert ingredients to be listed in the basic CSF. Active and inert ingredients listed in the basic CSF must come from only one source. Alternate suppliers can be listed in an alternate CSF. As many suppliers as possible are allowed in one alternate CSF (the word "or" can be used), as long as the inert ingredients used are specific only to a production site, i.e., US vs. non-Us production sites. Specific names and addresses for all suppliers are required.

THIS REVIEW CONTAINS FIFRA CBI

The registrant should refer to the reverse side of EPA Form 8570-4 for instructions in completing a CSF.

The following issues must also be resolved: (a) under box 3, correct the product name to read "CyLence Ultra Insecticide Cattle Ear Tag" for consistency with the product label; (b) under box



Other information on the CSFs is acceptable. The nominal concentrations of the active ingredients agree with that on the draft label, meeting PR Notice 91-2. The certified limits for the active ingredients and inert ingredients are acceptable in accordance with 40 CFR §158.175(b)(2). All ingredients are cleared for use in pesticide formulations.

The data reported in MRID Nos. 451597-01 and 478509-01 satisfy the product chemistry requirements as specified in 40 CFR §158.155, 158.160, 158.165, 158.167, 158.175, and 158.180 (the new 40 CFR section numbers are 158.320, 158.325, 158.335, 158.340, 158.350, and 158.355, respectively) which pertain to Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method.

The data also satisfy the product chemistry requirements as specified in 40 CFR §158.190 (the new 40 CFR number is 158.310) which pertain to the Physical and Chemical properties of the product.

- 4. The Enforcement Analytical Method for the determination of active ingredient content in the product is presented in MRID No. 451597-01 (and MRID No. 478509-01). The method is adequate and satisfies the requirements under Guideline 830.1800.
- 5. The Ingredients Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2 and 97-6. No data are present to trigger the need for a Physical or Chemical Hazards Statement. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3. The following revision to the label is recommended: place the Storage and Disposal Statements in a text box for prominence.

NOTE TO CRM: The labeling issues should be addressed during label review.

CONCLUSIONS:

After submission of revised CSFs, as noted in Finding 2, the registrant will satisfy the product chemistry requirements for the reregistration of EPA Reg. No. 11556-131.

Product Chemistry Data

Subgroup A: Guidelines Series 830.1550 - 830.1800 (40 CFR §158.320 - 158.355) Product Identity, Composition, and Analysis

Guideline Reference No. (GRN) / Title 830	40 CFR §	MRID Number	Data Fulfilled
830.1550 Product Identity and Composition	158.320	451597-01 and CSFs	Y
830.1600 Description of Materials Used to Produce the Product	158.325	451597-01 and CSFs	Y
830.1620 Description of Production Process	158.330	[Not required for products produced by a non-integrated system]	NR
830.1650 Description of Formulation Process	158.335	451597-01 and CSFs	Y
830.1670 Discussion of Formation of Impurities	158.340	451597-01	Y
830.1700 Preliminary Analysis	158.345	[Not required for products produced by a non-integrated system]	NR
830.1750 Certified Limits	158.350	451597-01 and CSFs	Y
830.1800 Enforcement Analytical Method	158.355	451597-01 (and 478509- 01)	Y

Subgroup B: Guideline Series 830.6302 - 830.7950 (40 CFR §158.310) Physical and Chemical Properties

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	Purple (added as opacifier and coloring agent)	451597-01	Y
.6303 Physical State	Solid at 25° C	451597-01	Y
.6304 Odor	Plastic odor	451597-01	Y

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6314 Oxidation/ Reduction: Chemical Incompatibility	Will not act as an oxidizing or reducing agent.	451597-01	Y
.6315 Flammability/Flame Extension	Not applicable. The product is a solid.	451597-01	N/A
.6316 Explodability	Not applicable.	451597-01	N/A
	Note: The product is a solid (plastic matrix).		
.6317 Storage Stability	Beta Cyfluthrin	478509-01	Y
,	Time Point Active		
	Conc.		
	Initial 8.2%		
	3 months 8.4%		
	6 months 8.1%		
	9 months 8.2%		
	12 months 7.8%		
	18 months 8.1%		
	24 months 8.2%		
	PBO		
	Time Point Active		
	Conc.		
	Initial 19.9%		
	3 months 19.7%		
	6 months 20.0%		
	9 months 20.2%		
	12 months 20.1%		
	18 months 19.7%		
	24 months 20.1%		
	Results demonstrate		
	stability for 24 months at		
	ambient temperature. No significant change in the		
	concentrations of the		
	active ingredients was		,
	observed over the 24-		
	month interval. Product		
	appearance and physical		
	characteristics were		

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
	acceptable through the 24-month interval. Some matrix bleeding was observed (a powder did uniformly migrate to the surface of the tags). All tags remained flexible over the 24-month interval. The product was tested in a foil pouch.		
.6319 Miscibility	Not applicable. The product is a solid.	451597-01	N/A
.6320 Corrosion Characteristics	Results demonstrate that the product is not corrosive to its packaging after storage for 24 months at ambient temperature. No corrosion was observed. The product was tested in a foil pouch.	478509-01	Y
	Non-corrosive.	451597-01	
.6321 Dielectric Breakdown Voltage	Not applicable. The product is a solid.	451597-01	N/A
.7000 рН	Not applicable. The product is a solid.	451597-01	N/A
.7100 Viscosity	Not applicable. The product is a solid.	451597-01	N/A
.7300 Density/Relative Density	1.337 (specific gravity)	451597-01	Y

Explanations: Y =Requirement fulfilled; N =Requirement not fulfilled; N/A =Not applicable; G =Data gap; U =Upgradeable; I =Incomplete or in progress; W =Waived; NR =Not required

Enforcement Analytical Method, Guideline 830.1800 (MRID No. 451597-01 (and MRID No. 478509-01))

A GC method with flame ionization detection is used to determine active ingredient content in the product ("Analysis of 8% Beta Cyfluthrin and 20% Piperonyl Butoxide in M779 Cattle Ear Tags"). The method has been validated. The method provides procedures for preparing standards and samples, a description of the instrument system, and equations for calculations. This method is found to be adequate and would satisfy Guideline 830.1800.

The GC system consists of the following:

Instrumentation:

Hewlett Packard 5890 or equivalent, equipped with a FID

Column:

30 meter 0.530 mm DB-17, 1 micron film thickness

Initial Oven Temperature:

210° C (hold for 2 min)

Final Oven Temperature:

260° C

Temperature Ramp: Injector Temperature: 7° C/min 275° C

Detector Temperature: 300° C

Injection Volume:

1 μL 25 min

Run Time: Carrier Gas:

Helium

Carrier Gas Flow Rate: 20 mL/min

FID Gases:

Hydrogen and Air

FID Gas Flow Rate:

Adjust to optimize flame and signal, see manufacturer of gas

chromatograph for recommended parameters

Confidential Appendix A

830.1550 Product Identity and Composition

EPA Reg. No. 11556-131 is an end-use product produced by a non-integrated system. The product contains the active ingredients, Beta Cyfluthrin and PBO, with label claim nominal concentrations of 8% and 20%, respectively. Sources of the active ingredients include the following registered products:

Nominal concentrations and upper/lower certified limits are identified in MRID No. 451597-01 and on the CSFs.

830.1600 Description of Materials Used to Produce the Product

The starting materials used in the formulation of EPA Reg. No. 11556-131 are identified in MRID No. 451597-01 and on the CSFs. Technical specifications were not provided; however, MSDSs were found to be available on the Internet for each inert formulation component.

830.1650 Description of Formulation Process

The formulation process is described in MRID No. 451597-01, as follows:

Manufacturing process information may be entitled to confidential treatment

Finished Product Specifications and Methods

Physical Description: A plastic matrix injection molded, purple, solid tag approximately 2.5

inches long x 2.5 inches wide and 1/8 inches thick and weighing

approximately 14 grams with a plastic odor.

Identification: The retention times observed for PBO and Beta Cyfluthrin in the sample

are similar to those observed in the PBO and Beta Cyfluthrin standard from chromatographs obtained during assay (for PBO ± 0.1 minutes and

for Beta Cyfluthrin ± 0.2 minutes).

PBO: 19.0-21.0% w/w

Beta Cyfluthrin: 7.6-8.4% w/w

830.1670 Discussion of Formation of Impurities

A discussion of impurity formation is provided in MRID No. 451597-01.

The product is not likely to form unintentional ingredients during manufacturing.

830.1750 Certified Limits

The CSF for the basic formulation, dated 2/9/2010, provides the following certified limits for the active ingredient sources and active ingredients:

Component	Lower Certified Limit	Nominal Concentration	Upper Certified Limit
		% by weight	
Beta Cyfluthrin source			
Beta Cyfluthrin	(7.6)	(8.0)	(8.4)
PBO source			·
PBO	(19.0)	(20.0)	(21.0)

Upper and lower certified limits for the active ingredients and inert ingredients are standard (or within the standard certified limit range).

DATE OUT: 21/SEP/2010

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP []; EUP [X]

BARCODE NO.: D374684 **REG./FILE SYMBOL NO.:** 11556-131

PRODUCT NAME: CyLence Ultra Insecticide Cattle Ear Tag

MRID NOS.: 451597-01 and 478509-01

COMPANY NAME: Bayer HealthCare, LLC

___ACTION CODE: <u>676</u>

CONTRACTOR: CSC

PROJECT CODE: PRD-173 OPII

FROM:

Maria Rivera Piansay, Chemist

Product Chemistry Team

Risk Management and Implementation Branch V Pesticide Re-evaluation Division (7508P)

TO:

Julia Stokes, CRM

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

INTRODUCTION:

A Reregistration Eligibility Decision (RED), Case number 2525, was issued on June 14, 2006 for the Technical Grade Active Ingredient (TGAI) Piperonyl Butoxide (PBO). According to the RED, the generic data base supporting the reregistration of Piperonyl Butoxide for currently registered uses has been reviewed and found to be substantially complete.

In the 8-month response to the Piperonyl Butoxide (PBO) RED, Bayer HealthCare, LLC provided a Confidential Statements of Formula (CSF), one basic and one alternate formulation, both dated 2/9/2010; EPA Form 8570-35 (Data Matrix), dated 2/8/2010; and a draft label, dated 2/10/2010; and cited product chemistry data, in MRID Nos. 451597-01 and 478509-01. The registrant is requesting reregistration of their product, CyLence Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131.

FINDINGS:

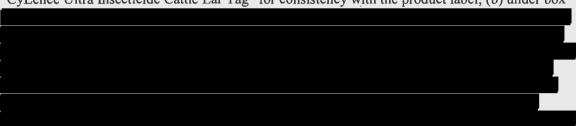
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- 2. The CSFs for the basic and alternate formulation are not acceptable. The Registration Division (RD) and the Pesticide Re-evaluation Division (PRD) are no longer allowing alternate sources of active ingredients and inert ingredients to be listed in the basic CSF. Active and inert ingredients listed in the basic CSF must come from only one source. Alternate suppliers can be listed in an alternate CSF. As many suppliers as possible are allowed in one alternate CSF (the word "or" can be used), as long as the inert ingredients used are specific only to a production site, i.e., US vs. non-Us production sites. Specific names and addresses for all suppliers are required.

THIS REVIEW CONTAINS FIFRA CBI

2

The registrant should refer to the reverse side of EPA Form 8570-4 for instructions in completing a CSF.

The following issues must also be resolved: (a) under box 3, correct the product name to read "CyLence Ultra Insecticide Cattle Ear Tag" for consistency with the product label; (b) under box



Other information on the CSFs is acceptable. The nominal concentrations of the active ingredients agree with that on the draft label, meeting PR Notice 91-2. The certified limits for the active ingredients and inert ingredients are acceptable in accordance with 40 CFR §158.175(b)(2). All ingredients are cleared for use in pesticide formulations.

3. The data reported in MRID Nos. 451597-01 and 478509-01 satisfy the product chemistry requirements as specified in 40 CFR §158.155, 158.160, 158.165, 158.167, 158.175, and 158.180 (the new 40 CFR section numbers are 158.320, 158.325, 158.335, 158.340, 158.350, and 158.355, respectively) which pertain to Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method.

The data also satisfy the product chemistry requirements as specified in 40 CFR §158.190 (the new 40 CFR number is 158.310) which pertain to the Physical and Chemical properties of the product.

- 4. The Enforcement Analytical Method for the determination of active ingredient content in the product is presented in MRID No. 451597-01 (and MRID No. 478509-01). The method is adequate and satisfies the requirements under Guideline 830.1800.
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NOTE TO CRM: The labeling issues should be addressed during label review.

CONCLUSIONS:

After submission of revised CSFs, as noted in Finding 2, the registrant will satisfy the product chemistry requirements for the reregistration of EPA Reg. No. 11556-131.

Product Chemistry Data

Subgroup A: Guidelines Series 830.1550 - 830.1800 (40 CFR §158.320 - 158.355) Product Identity, Composition, and Analysis

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830.1700 Preliminary Analysis	158.345	[Not required for products produced by a non-integrated system]	NR
830.1750 Certified Limits	158.350	451597-01 and CSFs	Y
830.1800 Enforcement Analytical Method	158.355	451597-01 (and 478509- 01)	Y

Subgroup B: Guideline Series 830.6302 - 830.7950 (40 CFR §158.310) Physical and Chemical Properties

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	Purple (added as opacifier and coloring agent)	451597-01	Y
.6303 Physical State	Solid at 25° C	451597-01	Y
.6304 Odor	Plastic odor	451597-01	Y

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6314 Oxidation/ Reduction: Chemical Incompatibility	Will not act as an oxidizing or reducing agent.	451597-01	Y
.6315 Flammability/Flame Extension	Not applicable. The product is a solid.	451597-01	N/A
.6316 Explodability	Not applicable. Note: The product is a solid (plastic matrix).	451597-01	N/A
.6317 Storage Stability	Beta Cyfluthrin Time Point Active Conc. Initial 8.2% 3 months 8.4% 6 months 8.1% 9 months 8.2% 12 months 7.8% 18 months 8.1% 24 months 8.2%	478509-01	Y .
	PBO Time Point Active Conc. Initial 19.9% 3 months 19.7% 6 months 20.0% 9 months 20.2% 12 months 20.1% 18 months 19.7% 24 months 20.1%		
	Results demonstrate stability for 24 months at ambient temperature. No significant change in the concentrations of the active ingredients was observed over the 24-month interval. Product appearance and physical characteristics were		

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
·	acceptable through the 24-month interval. Some matrix bleeding was observed (a powder did uniformly migrate to the surface of the tags). All tags remained flexible over the 24-month interval. The product was tested in a foil pouch.		
.6319 Miscibility	Not applicable. The product is a solid.	451597-01	N/A
.6320 Corrosion Characteristics	Results demonstrate that the product is not corrosive to its packaging after storage for 24 months at ambient temperature. No corrosion was observed. The product was tested in a foil pouch.	478509-01	Y
	Non-corrosive.	451597-01	
.6321 Dielectric Breakdown Voltage	Not applicable. The product is a solid.	451597-01	N/A
.7000 pH	Not applicable. The product is a solid.	451597-01	N/A
.7100 Viscosity	Not applicable. The product is a solid.	451597-01	N/A
.7300 Density/Relative Density	1.337 (specific gravity)	451597-01	Y

Explanations: Y =Requirement fulfilled; N =Requirement not fulfilled; N/A =Not applicable; G =Data gap; U =Upgradeable; I =Incomplete or in progress; W =Waived; NR =Not required

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The GC system consists of the following:

Instrumentation:

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Column:

30 meter 0.530 mm DB-17, 1 micron film thickness

Initial Oven Temperature:

210° C (hold for 2 min)

Final Oven Temperature: Temperature Ramp:

260° C

Injector Temperature:

7° C/min 275° C

Detector Temperature: 300° C

Injection Volume:

 $1 \mu L$

Run Time: Carrier Gas: 25 min Helium

Carrier Gas Flow Rate: 20 mL/min

FID Gases:

Hydrogen and Air

FID Gas Flow Rate:

Adjust to optimize flame and signal, see manufacturer of gas

chromatograph for recommended parameters

Confidential Appendix A

830.1550 Product Identity and Composition

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approximately 14 grams with a plastic odor.

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PBO source					
PBO	(19.0)	(20.0)	(21.0)		

Upper and lower certified limits for the active ingredients and inert ingredients are standard (or within the standard certified limit range).

THIS REVIEW CONTAINS FIFRA CBI

Generic and Product Specific Data Call-In Notice

CyLence Ultra Insecticide Cattle Ear Tag (EPA Reg. No. 11556-131)

Ingredient Name: Piperonyl Butoxide – Case #2525

Request for Waivers for Certain Acute Toxicity Study Requirements

The acute toxicity studies normally associated with a formulated product were not conducted because they are not practical or necessary for a cattle ear tag. In explanation, the physical nature of the product, which is a plastic ear tag, is not a practical test article for the conduct of: a) acute oral toxicity, b) acute inhalation toxicity, c) primary eye irritation, d) primary dermal irritation, or e) dermal sensitization. These aforementioned studies were waived when the original registration was granted (see EPA memoranda, dated 07 June 2002 and 13 Sept 2001; both attached). An acceptable study (MRID 45640701) is on file with the Agency for the acute dermal toxicity (870.1200) data requirement.

We therefore request the respective waivers for the following data requirements for the subject end-use product containing Piperonyl Butoxide:

- a) acute oral toxicity (870.1100)
- b) acute inhalation toxicity (870.1300)
- c) primary eye irritation (870.2400)
- d) primary dermal irritation (870.2500)
- e) dermal sensitization (870.2600)

Attachments:

- 1. EPA memoranda, dated 07 June 2002
- 2. EPA memoranda, dated 13 Sept 2001



To:

doug.spilker.b@bayer.com,

Cc: Bcc:

Subject: PBO product EPA Reg. No. 11556-131

From: Julia Stokes/DC/USEPA/US - Thursday 04/15/2010 08:34 AM

Good Morning Doug,

With regard to the request to waive acute toxicity data requirements for Bayer's PBO product EPA Reg. No. 11556-131 Mark Perry has approved the waiver request for Guideline 870.2600 after receiving your justification in email. This product is still in acute toxicity review but I took a look and all looks good.

CONFIRM RECEIPT of this EMAIL

(ALL Confidential Business Information (CBI) MUST be mailed to the Agency via Document Processing Desk)

Thank you, Julia M. Stokes

Chemical Review Manager Risk Management and Implementation Branch (RMIB5) Pesticide Re-Evaluation Division (7508P) EPA/OPPTS/OPP (703) 347-8966 stokes.julia@epa.gov

Visit: http://www.epa.gov/pesticides



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mar 23, 2010

MEMORANDUM:

Subject:

EPA Reg. No.: 11556-131/Cylence® Ultra Insecticide Cattle Ear TAG

DP Barcode: 374683

From:

Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

Julia Stokes, CRM
Risk Management

To:

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

Applicant:

Bayer HealthCare, LLC,

Animal Health Division

P.o Box 390

Shawnee Mission, KS 66201-0390

FORMULATION FROM EPA Reg. No. 11556-131 LABEL:	<u>% by wt.</u>
Active Ingredient(s):	
Beta-cyfluthrin:	8%
Piperonyl butoxide:	20%
Inert Ingredient(s):	<u>72%</u>
Total:	100%

BACKGROUND: In the 8 month response to the PBO (067501) RED, the registrant is submitting data regarding acute toxicity studies to support the reregistration of their product, EPA Reg. No. 11556-131. Five of the acute toxicity studies (81-1, 81-3, 81-4, 81-5 and 81-6) were waived by the Agency in Sep 2001. The Acute dermal toxicity study (81-2) bearing MRID:456407-01, conducted at Bayer Corporation Agricultural Division, Toxicology, was reviewed and found to be acceptable by TRB/RD on 6/7/02. The test substance was 20% PBO and 8% beta-cyfluthrin. After verifying the CSF, RMIB V concurs with RD findings.

RECOMMENDATIONS:

- Five of the acute toxicity studies (81-1, 81-3, 81-4, 81-5 and 81-6) were waived.
- The Acute dermal toxicity study (81-2) was found to be acceptable to support the reregistration of EPA Reg. No. 11556-131.

The acute toxicity profile for EPA Reg. No. 11556-131 is currently:

Acute Oral	IV	Waived
Acute Dermal	III	Acceptable
Acute Inhalation	IV	Waived
Primary Eye	IV	Waived
Primary Dermal	IV	Waived
Skin Sensitization	Non sensitizer	Waived

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 011556-00131

CYLENCE® ULTRA INSECTICIDE CATTLE EAR TAG

SIGNAL WORD:

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS*:

Harmful if absorbed through skin. Avoid contact with skin, eyes or on clothing. Wear long-sleeved shirt and long pants, socks and shoes, and chemical resistant gloves (such as or made out of any waterproof material, selection category A).

*If Selection Category A gloves does not provide adequate protection for this product, the registrant should indicate a specific glove category from the EPA chemical resistance chart that will provide adequate protection.

FIRST AID:

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mar 23, 2010

MEMORANDUM:

Subject:

EPA Reg. No.: 11556-131/Cylence® Ultra Insecticide Cattle Ear TAG

DP Barcode: 374683

Case No.: 2525

From:

Santa K. Vinjamuri, Biologist
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

Julia Stokes. CRM

To:

Risk Management and Implementation Branch V

Pesticide Re-evaluation Division (7508P)

Applicant:

Bayer HealthCare, LLC,

Animal Health Division

P.o Box 390

Shawnee Mission, KS 66201-0390

FORMULATION FROM EPA Reg. No. 11556-131 LABEL:	<u>% by wt.</u>
Active Ingredient(s):	
Beta-cyfluthrin:	8%
Piperonyl butoxide:	20%
<pre>Inert Ingredient(s):</pre>	72%
Total:	100%

BACKGROUND: In the 8 month response to the PBO (067501) RED, the registrant is submitting data regarding acute toxicity studies to support the reregistration of their product, EPA Reg. No. 11556-131. Five of the acute toxicity studies (81-1, 81-3, 81-4, 81-5 and 81-6) were waived by the Agency in Sep 2001. The Acute dermal toxicity study (81-2) bearing MRID:456407-01, conducted at Bayer Corporation Agricultural Division, Toxicology, was reviewed and found to be acceptable by TRB/RD on 6/7/02. The test substance was 20% PBO and 8% beta-cyfluthrin. After verifying the CSF, RMIB V concurs with RD findings.

RECOMMENDATIONS:

- Five of the acute toxicity studies (81-1, 81-3, 81-4, 81-5 and 81-6) were waived.
- The Acute dermal toxicity study (81-2) was found to be acceptable to support the reregistration of EPA Reg. No. 11556-131.

The acute toxicity profile for EPA Reg. No. 11556-131 is currently:

Acute Oral	IV	Waived
Acute Dermal	III	Acceptable
Acute Inhalation	IV	Waived
Primary Eye	IV	Waived
Primary Dermal	IV	Waived
Skin Sensitization	Non sensitizer	Waived

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 011556-00131

CYLENCE® ULTRA INSECTICIDE CATTLE EAR TAG

SIGNAL WORD:

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS*:

Harmful if absorbed through skin. Avoid contact with skin, eyes or on clothing. Wear long-sleeved shirt and long pants, socks and shoes, and chemical resistant gloves (such as or made out of any waterproof material, selection category A).

*If Selection Category A gloves does not provide adequate protection for this product, the registrant should indicate a specific glove category from the EPA chemical resistance chart that will provide adequate protection.

FIRST AID:

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

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User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.



Fw: PBO EPA Reg. No. 11556-131 Acute Toxicity Waiver Requests -

Follow-up

Mark Perry to: Julia Stokes

02/18/2010 07:49 AM

Julia,

Per the additional rationale provided by the registrant (below) and based on an evaluation of the inert of concern in the product formulation (indicating no sensitization potential), a waiver will be granted for the dermal sensitization requirement for EPA Reg. No. 11556-131. Please let me know if you have any questions.

Mark Perry RMIB V PRD

---- Forwarded by Mark Perry/DC/USEPA/US on 02/18/2010 07:41 AM -----

From:

Doug Spilker <doug.spilker.b@bayer.com>

To: Cc: Mark Perry/DC/USEPA/US@EPA
Julia Stokes/DC/USEPA/US@EPA

Date:

02/17/2010 09:42 AM

Subject:

Re: PBO EPA Reg. No. 11556-131 Acute Toxicity Waiver Requests - Follow-up

Dear Mr. Perry,

Ms. Stokes in her message below directed me to send my questions to you regarding our waiver request for specific acute toxicity studies as related to the PBO PDCI.

In explanation, as the product name - CyLence Ultra Insecticide Cattle Ear Tag - implies, this product is an insecticide cattle ear tag. As such, the plastic form of this product (and all other cattle ear tags) does not lend itself for the conduct of the standard "six pack" of the acute toxicity studies. The Agency has acknowledged this in the original acute tox review (see attached review 06/07/02) to support the registration of the product. We were only required to conduct the Acute Dermal Toxicity Study, and it was found acceptable. Therefore, it was our assumption that no additional studies would be required to support this end-use formulation. Furthermore, we were granted the same waivers for the recent registrations of two new cattle ear tags (see attached reviews, both dated 2/12/09). As you will note in the reviews that this strategy was agreed to in our pre-registration meetings with the Agency in 2008.

However, we were notified in Ms. Stokes email of 2/16/10 (attached), almost 5 months after submission of our request, that the waiver request for Guideline 870.2600 was disapproved for this product. Since as outlined above, the precedent for conduct of acute toxicity studies was previously set and we had not heard anything from the Agency to the contrary, we were quite surprised that our waiver was rejected. Since we had not heard anything from the Agency regarding our September 2009 submission, we made our 8-month PDCI response on 2/12/2010 (attached) noting the respective waiver request.

We therefore ask the Agency to reconsider our waiver request for Guideline 870.2600, based on the

aforementioned previous guidance from the Agency.

Sincerely,

Doug Spilker

Douglas A. Spilker, Ph.D. Manager - EPA Reg. Affairs BAYER HEALTHCARE LLC ANIMAL HEALTH Office: +1 913-268-2751

Office: +1 913-268-2751 Mobile: +1 816-506-3102 Fax: +1 913-268-2135

Email: doug.spilker.b@bayer.com

Address: P.O. Box 390 Shawnee Mission, KS 66201-0390 Country: USA

Bayer Animal Health "Protecting.Curing.Caring...Together"

Stokes.Julia@epamail.epa.gov

To Doug Spilker <doug.spilker.b@bayer.com>

02/17/2010 07:13 AM

Subject PBO EPA Reg. No. 11556-131 Acute Toxicity Waiver Requests

Doug,

I received your phone message this morning and have spoken to our acute toxicity Team Leader Mark Perry and he asks that you email him any questions you might have about PBO product EPA Reg. No. 11556-131 and the acute toxicity waiver requests you submitted.

Mark Perry- Perry.Mark@epa.gov

CONFIRM RECEIPT of this EMAIL (ALL Confidential Business Information (CBI) MUST be mailed to the Agency via Document Processing Desk)

Thank you, Julia M. Stokes

Chemical Review Manager Risk Management and Implementation Branch (RMIB5) Pesticide Re-Evaluation Division (7508P) EPA/OPPTS/OPP (703) 347-8966 stokes.julia@epa.gov

Visit: http://www.epa.gov/pesticides

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Re: PBO EPA Reg. No. 11556-131 Acute Toxicity Waiver Requests -

Follow-up

Doug Spilker to: Mark Perry

Cc: Julia Stokes

02/17/2010 09:42 AM

Dear Mr. Perry,

Ms. Stokes in her message below directed me to send my questions to you regarding our waiver request for specific acute toxicity studies as related to the PBO PDCI.

In explanation, as the product name - CyLence Ultra Insecticide Cattle Ear Tag - implies, this product is an insecticide cattle ear tag. As such, the plastic form of this product (and all other cattle ear tags) does not lend itself for the conduct of the standard "six pack" of the acute toxicity studies. The Agency has acknowledged this in the original acute tox review (see attached review 06/07/02) to support the registration of the product. We were only required to conduct the Acute Dermal Toxicity Study, and it was found acceptable. Therefore, it was our assumption that no additional studies would be required to support this end-use formulation. Furthermore, we were granted the same waivers for the recent registrations of two new cattle ear tags (see attached reviews, both dated 2/12/09). As you will note in the reviews that this strategy was agreed to in our pre-registration meetings with the Agency in 2008.

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We therefore ask the Agency to reconsider our waiver request for Guideline 870.2600, based on the aforementioned previous guidance from the Agency.

Sincerely,

Doug Spilker

Douglas A. Spilker, Ph.D. Manager - EPA Reg. Affairs BAYER HEALTHCARE LLC ANIMAL HEALTH

Office: +1 913-268-2751 Mobile: +1 816-506-3102 Fax: +1 913-268-2135

Email: doug.spilker.b@bayer.com

Address: P.O. Box 390 Shawnee Mission, KS 66201-0390 Country: USA

Bayer Animal Health "Protecting.Curing.Caring...Together"

Stokes.Julia@epamail.epa.gov

To Doug Spilker <doug.spilker.b@bayer.com>

CC

02/17/2010 07:13 AM

Subject PBO EPA Reg. No. 11556-131 Acute Toxicity Waiver Requests

Doug

I received your phone message this morning and have spoken to our acute toxicity Team Leader Mark Perry and he asks that you email him any questions you might have about PBO product EPA Reg. No. 11556-131 and the acute toxicity waiver requests you submitted.

Mark Perry- Perry.Mark@epa.gov

CONFIRM RECEIPT of this EMAIL (ALL Confidential Business Information (CBI) MUST be mailed to the Agency via Document Processing Desk)

Thank you, Julia M. Stokes

Chemical Review Manager
Risk Management and Implementation Branch (RMIB5)
Pesticide Re-Evaluation Division (7508P)
EPA/OPPTS/OPP
(703) 347-8966
stokes.julia@epa.gov

Visit: http://www.epa.gov/pesticides

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Cylence Ultra CET Waiver request 091009.pdf CyLence Ultra CET Acute Tox review 060702.pdf



M910 CET Acute Tox rev 021209.pdf M904 CET Acute Tox rev 021209.pdf Waiver Denial email 021610.pdf



100'd 2/16/10

Reason to Issue:

Propose ReRegistration of product [with DCI Response]

∟ ...9:

02/10/2010

Supersedes:

05/28/2008

Page 1 of 6

Pouch

CYLENCE® ULTRA INSECTICIDE CATTLE EAR TAG

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks for Up to Five Months.

		Percent By Weight
Active Ingredients	Beta-cyfluthrin	8%
	Piperonyl butoxide	20%
Other Ingredients		72%
Total		100%

Keep Out of Reach of Children

CAUTION

See Box For Precautionary Statements

Net Contents: 10 Tags - 0.5 oz per tag

Manufactured for Bayer HealthCare, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201 U.S.A.

> EPA Est. No. 67517-MO-1 EPA Reg. No. 11556-131

Propuse ReRegistration of product [with

DCI Response]

Luie:

02/10/2010

Supersedes:

05/28/2008

Page 2 of 6

Box (Front)

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For Use with Allflex Universal Total Tagger with red pin and black clip.

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks

- Effective Against Face Flies and Pyrethroid Susceptible Horn Flies for up to 5 months.
- Kills and Repels Face Flies mechanical vector of *Moraxella bovis* bacteria causing "pink eye" of cattle
- Synergized for extra performance

		Percent By Weight
Active Ingredients	Beta-cyfluthrin	8%
	Piperonyl Butoxide Technical	20%
Other Ingredients		72%
Total		100%

Keep Out of Reach of Children CAUTION

See Side Panel for Additional Precautionary Statements

Net Contents: 2 pouches of 10 tags each – 0.5 oz per tag

Bayer HealthCare, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201 U.S.A.

Prop _e ReRegistration of product [with

DCI Response]

L ... 2:

02/10/2010

Supersedes:

05/28/2008

Page 3 of 6

Box (Side Panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

May cause eye irritation. Harmful if swallowed, inhaled or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wear nonpermeable protective gloves when applying or removing tags. Wash thoroughly with soap and water after use and before eating, drinking or using tobacco.

FIRST AID

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If Swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If Inhaled:

- Move person to fresh air.
- If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment, call 1-800-422-9874. For customer service or to obtain product information, including MSDS, call 1-800-633-3796.

Environmental Hazards: This pesticide is toxic to fish. Do not contaminate water when disposing of used tags. Apply this product only as specified on the label.

Propuse ReRegistration of product [with

DCI Response]

Luie:

02/10/2010

Supersedes:

05/28/2008

Page 4 of 6

Box (Back)

Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating).

All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. CyLence® Ultra Insecticide Ear Tags have been proven to be effective against face and horn flies for up to five months.

Use the Allflex Universal Total Tagger with the red pin and black clip to apply tags to cattle.

Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

(Illustration)	(Illustration)	(Illustration)	(Illustration)
Figure 1	Figure 2	Figure 3	Figure 4
Disinfect pliers prior to use. Place male button onto pin until it projects through the tip.	Slide tag under the clip of the pliers by depressing the lever.	Position tag in the center portion of the front side of the ear.	Apply the tag between the second and third rib cartilage.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. CyLence® Ultra Cattle Ear Tag contains the pyrethroid insecticide beta-cyfluthrin plus piperonyl butoxide, which is an insecticide synergist.

Pro_k a ReRegistration of product [with

DCI Response]

∟ ..e:

02/10/2010

Supersedes:

05/28/2008

Page 5 of 6

Box (Back)

Storage and Disposal:

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned stay out of smoke.

EPA Est. No. 67517-MO-1 EPA Reg. No. 11556-131

Prop. a ReRegistration of product [with

DCI Response]

Luie:

02/10/2010

Supersedes:

05/28/2008

Page 6 of 6

Box (Side Panel)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.



<u>To</u>:

Doug Spilker <doug.spilker.b@bayer.com>

Cc:

Bcc:

Subject: Re: PBO Waiver Request for EPA Reg. No. 11556-131

From: Julia Stokes/DC/USEPA/US - Tuesday 02/16/2010 12:28 PM

Doug,

I have recently received the results of the Acute Toxicity waiver request submitted at the 90-Day Response for EPA Reg. No. 11556-131. Let this email serve as notification that the acute toxicity waiver request for 870.1100, 870.1300, 870.2400, and 870.2500 has been approved. The waiver request for Guideline 870.2600 has been disapproved. Please submit information on sensitizing potential of each ingredient (including inerts) for further review. Submit with the 8-Month Response due 3-16-10.

CONFIRM RECEIPT of this EMAIL

(ALL Confidential Business Information (CBI) MUST be mailed to the Agency via Document Processing Desk)

Thank you, Julia M. Stokes

Chemical Review Manager
Risk Management and Implementation Branch (RMIB5)
Pesticide Re-Evaluation Division (7508P)
EPA/OPPTS/OPP
(703) 347-8966
stokes.julia@epa.gov

Visit: http://www.epa.gov/pesticides

Doug Spilker Dear Ms. Stokes, I am preparing my response to...

02/08/2010 03:09:16 PM

From:

Doug Spilker <doug.spilker.b@bayer.com>

To:

Julia Stokes/DC/USEPA/US@EPA

Date: Subject: 02/08/2010 03:09 PM PBO PDCI Question

Dear Ms. Stokes.

I am preparing my response to the PBO DCI, and am uncertain how I respond to the acute toxicity requirements. We have one product, CyLence Ultra Insecticide Cattle Ear Tag (11556-131), which contains PBO. With the original registration, we received waivers for all but the acute dermal toxicity study (see attached). Do I need to request waivers again, or can I just cite the review?

Thanks for your guidance.
Doug

Douglas A. Spilker, Ph.D. Manager - EPA Reg. Affairs BAYER HEALTHCARE LLC ANIMAL HEALTH Office: +1 913-268-2751 Mobile: +1 816-506-3102 Fax: +1 913-268-2135

Email: doug.spilker.b@bayer.com

Address: P.O. Box 390 Shawnee Mission, KS 66201-0390 Country: USA

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For alternate languages please go to http://bayerdisclaimer.bayerweb.com [attachment "CyLence Ear Tag Acute Tox review.pdf" deleted by Julia Stokes/DC/USEPA/US]

Bayer HealthCare Animal Health



Via Federal Express

February 12, 2010

Document Processing Desk (DCI/SRRD)

Ms. Julia Stokes, Chemical Review Manager

Product Reregistration Branch

Special Review and Reregistration Branch 7508P

U.S. Environmental Protection Agency

One Potomac Yard (South Building)

2777 South Crystal Drive

Arlington, VA 22202

Subject: APPLICATION FOR PESTICIDE REREGISTRATION OF:

CyLence Ultra Insecticide Cattle Ear Tag

EPA Reg No.: 11556-131

8-Month Response to Product Specific Data Call-In Letter,

June 16, 2009

Ingredient Name: Piperonyl Butoxide – Case #2525

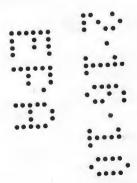
Bayer HealthCare LLC Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390

Dear Ms. Stokes:

This is in response to the subject DCI Letter from EPA (Richard P. Keigwin) dated June 16, 2009, concerning the reregistration of the subject product.

The contents and attachments to this response and Application for Pesticide Reregistration of the subject product includes the following:

- 1. 90-day response, letter dated 9/10/2009 (D.A. Spilker to K. St. Clair)
- 2. Richard P. Keigwin letter dated June 16, 2009 (Pages 1 & 16 only)
- 3. EPA Memorandum, dated June 16, 2009 (Page 1)
- 4. "Data Call-In Response" Piperonyl Butoxide
- 5. "Requirements Status and Registrant's Response"
- Registrant Waiver request (additional copy of one sent with 90-day response), dated 9/10/2009
- Application for Pesticide Reregistration (EPA Form 8570-1), dated 2/12/2010
- Confidential Statement of Formula Basic (EPA Form 8570-4) (2 copies), dated 2/09/2010; with nonsubstantive updates from previous CSF (4/28/2003)



Office of Pesticide Programs (7508P)

February 12, 2010

- 9. Confidential Statement of Formula Alternate (EPA Form 8570-4) (2 copies), dated 2/09/2010; with nonsubstantive updates from previous CSF (4/3/2007)
- 10. EPA Currently Acceptable Confidential Statement of Formula Basic (EPA Form 8570-4); dated 4/28/2003
- 11. EPA Currently Acceptable Confidential Statement of Formula Alternate (EPA Form 8570-4); dated 4/3/2007 (letter dated 5/31/2007)
- 12. Formulator's Exemption Statement (EPA Form 8570-27)
- 13. Certification with respect to Citation of Data (EPA Form 8570-34)
- 14. Letter of Authorization from Bayer Crop Science for Betacyfluthrin, dated 6/22/2000 (still valid)
- 15. Data Matrix (EPA Form 8570-35), dated 2/08/2010
- 16. Data Matrix Public File Copy (EPA Form 8570-35), dated 2/08/2010
- 17. Draft Label Subject Product, draft dated 02/10/2010 (5 copies)
- 18. Latest Product Label on File with EPA (Notification dated 7/16/2008), label text date 05/28/2008
- 19. EPA Product Chemistry review, dated 10/17/2000
- 20. EPA Acute Toxicity review and prior waiver determination, dated 6/07/2002
- 21. Cylence Ultra PDMS Database Web Search NPIRSALL Available Data, dated 02/08/10 (6pp.)

Please note that this product was originally registered as *Cutter Ultra Insecticide Cattle Ear Tag* and later changed to CyLence Ultra Insecticide Cattle Ear Tag. Therefore, some of the Agency's documents may bear that name for the subject product.

If there are any questions concerning this response, please contact me by phone (913-268-2751) or e-mail (doug.spilker.b@bayer.com).

lagles A Gillen

Sincerely.

Douglas A. Spilker. Ph. D.

Manager, EPA Regulatory Affairs

Doug.Spilker.b@Bayer.com

DAS

ese read instructions on r	aumana badana cam	g form.			Form Ap	25014	AP No. 201	70-008/	D. Approval expires 2-28-95
EPA	Environmenta	Inited States	on Age	Registra		✓	Registrati Amendme	on	OPP Identifier Number
		Application	on for F	Pesticide	- Sec	tion	I		
Company/Product Number 11556				2. EPA Pro Kimbe	duct Mar erly Nes	_		3. Pro	posed Classification
Company/Product (Name) CyLer	nce Ultra Insecticio	de Cattle Ea	r Tag	PM#	13				Nosuicted
Name and Address of App ayer HealthCare LLC O. Box 390 nawnee Mission, KS	C, Animal Health			1	product J. No	is sim	nilar or identica		FIFRA Section 3(c)(3) mposition and labeling
			Sect	tion - II	IVAITIU				
Amendment - Explain Resubmission in responsible to the control of	below. al page(s) if necessar	γ. (For sectio		A *I	gency let Me Too" / ther - Exp	ter dat Applica plain be	ation. Blow.		tion for Pesticide
			Sect	ion - III					
Material This Product Will	Be Packaged In:								
Id-Resistant Packaging Yes No Certification must submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per container	Water :		No. per containe	r	- V F	ntainer Vietal Plastic Glass Paper Other (S	pecify)
ocation of Net Contents I	nformation	4. Size(s) Re		ner g 20 ear tag	s	5. Lo	Cation of Label On label	Directio	ns
Manner in Which Label is	Affixed to Product	Lithog Paper Stenc	raph glued iled		Othe	ır			
			Secti	ion - IV					
Contact Point (Complete	items directly below	for identification	on of indivi	idual to be c	ontacted,	if nec	essary, to proce	ess this	application.)
ne Douglas A. Spilk	er		Title Managei	r, EPA Reg	ulatory A	ffairs	₹ Te		No. (Include Area Code) 3) 268-2751
I certify that the stater I ecknowledge that en both under applicable I	knowlinglly false or		all attach						6. Date Application Reddived (Stamped)
signature Oly hor	1. Gille	-	3. Title	Manager, E	PA Regul	latory /	Affairs		•••
yped Name Douglas A. Spilke	er		5. Dete	Febru	ary 12	2, 20°	10		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Strategies Division (28221), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.					
Certification with Respect to Citation of Data					
Applicant's/Registrant's Name, Address, and Telephone Number Bayer HealthCare LLC, Animal Health Div, POB 390, Shawnee Mission, KS 66201	[913-268-2751]	EPA Registration Number/File Symbol 11556-131			
Active Ingredient(s) and/or representative test compound(s) Beta-cyfluthrin and Piperonyl Butoxcide		Date February 12, 2010			
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor		Product Name CyLence Ultra Insecticide Cattle Ear Tag			
NOTE: If your product is a 100% repackaging of another purchased EPA-registered submit this form. You must submit the Formulator's Exemption Statement (EPA Form		r all the same uses on your label, you do not need to			
I am responding to a Data-Call-In Notice, and have included with this form a I be used for this purpose).	ist of companies se	nt offers of compensation (the Data Matrix form should			
SECTION I: METHOD OF DATA SUPP	ORT (Check one me	ethod only)			
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under the	g the selective method of support (or cite-all option selective method), and have included with this form a d list of data requirements (the Data Matrix form must be			
SECTION II: GENERAL C	OFFER TO PAY				
[Required if using the cite-all method or when using the cite-all option under the select	·				
SECTION III: CERTI	FICATION				
application for registration, the form for reregistration, or the Data-Call-In response. In indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product; and (2) is	I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.				
I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.	or reregistration, tha	at I am the original data submitter or that I have obtained			
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.					
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.					
I certify that the statements I have made on this form and all attachme knowingly false or misleading statement may be punishable by fine or imprisor					
Signature / / / / /	Date	Typed or Printed Name and Title			
Signature Nachu A. Gellin	Feb 12, 2010	Douglas A. Spilker, Mgr, EPA Reg. Affairs			

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.



United States Environmental Protection Agency

Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address

Bayer Healthcare LLC Animal Health Division

P.O. Box 390

Shawnee Mission, KS 66201-0390

EPA File Symbol/Registration Number

11556-131

Product Name

CyLence Ultra Insecticide Cattle Ear Tag

Date of Confidential Statement of Formula (EPA Form 8570-4)

02/09/2010

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Beta -cyfluthrin

Piperonyl Butoxcide

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).
- (3) Indicate by checking (A) or (B) below which paragraph applies:
- (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

- (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.
- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source					
Active Ingredient	Product Name	Registration Number			
Piperonyl Butoxcide					
Signature	Name and Title	Date			
Notes A. Spelle	D.A. Spilker, EPA Reg. Affairs Mg	02/12/2010			
EPA Form 8570-27 (Rev. 06-2004)		Copy 1 – EPA Copy 2 - Applicant copy			



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DATA MATRIX						
Date February 8, 2010			EPA Reg No./File Symbol 11556-131 Page 1 of 8			
Applicant's/Registrant's Name & Address Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201 Product CyLence® Ultra Insecticide Cattle Ear Tag				g		
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5 Piperonyl Butoxcide - CAS # 51-03-6						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830.1550	PRODUCT CHEMISTRY Product identity and composition	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.1600	Description of materials used to produce product	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.1620	Description of production process	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.1650	Description of formulation process	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.1670	Discussion of formation of impurities	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.1700	Preliminary analysis	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.1750	Certified Limits	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.1800	Enforcement Analytical Method	45159701	11556	OWN	Bayer Report No. 75142 (EP)	



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DATA MATRIX								
Date February 8, 2010	·		EPA Reg No./File Symbol 11556-131		Page 2 of 8			
Applicant's/Registrant's Name & Address Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201								
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5 Piperonyl Butoxcide – CAS # 51-03-6								
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note			

830.1900	Submittal of Samples				Samples available upon request
830.6302	Color	45159701	11556	OWN	Bayer Report No. 75142 (EP)
830.6303	Physical State	45159701	11556	OWN	Bayer Report No. 75142 (EP)
830.6304	Odor	45159701	11556	OWN	Bayer Report No. 75142 (EP)
830.6313	Stability to normal and elevated temperatures	45159701	11556	OWN	Bayer Report No. 75142 (EP)
830.6314	Oxidizing or Reducing Action	45159701	11556	OWN	Bayer Report No. 75142 (EP)
830.6315	Flammability	45159701	11556	OWN	Bayer Report No. 75142 (EP)



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DATA MATRIX						
Date February 8, 2010		EPA Reg No./File Symbol 11556-131		Page 3 of 8		
Applicant's/Registrant's Name & Address	Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201	Product CyLence® Ultra Insecticide Cattle Ear Tag				
Ingredient Cyano(4-fluoro-3-phenoxyphen Piperonyl Butoxcide – CAS # 5	yl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethyld 1-03-6	cyclopropanecarboxylat	e - CAS # 68359-37-5			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830.6316	Explodability	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.6317	Storage Stability of Product	47850901	11556	OWN	Bayer Report No. 33716 (EP)	
830.6319	Miscibility	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.6319	Corrosion characteristics	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.6321	Dielectric breakdown	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.7000	рН	45159701	11556	OWN	Bayer Report No. 75142 (EP)	
830.7050	UV/Visible Absorption				N/A for EP	



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DATA MATRIX							
Date February 8, 2010		EPA Reg No./File Symbol 11556-131		Page 4 of 8			
Applicant's/Registrant's Name & Address	Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201	Product CyLence® Ultra Insecticide Cattle Ear Tag					
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5 Piperonyl Butoxcide - CAS # 51-03-6							
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note		
	1	1	Ι	I			
830.7100	Viscosity	45159701	11556	OWN	Bayer Report No. 75142 (EP)		
830.7200	Melting Point	45159701	11556	OWN	Bayer Report No. 75142 (EP)		
830.7220	Boiling Point	45159701	11556	OWN	Bayer Report No. 75142 (EP)		
830.7300	Density, bulk-density, or specific gravity	45159701	11556	OWN	Bayer Report No. 75142 (EP)		
830.7370	Dissociation constant	45159701	11556	OWN	Bayer Report No. 75142 (EP)		
830.7550	Octanol/water partition coefficient	45159701	11556	OWN	Bayer Report No. 75142 (EP)		
830.7840	Solubility	45159701	11556	OWN	Bayer Report No. 75142 (EP)		
830.7950	Vapor Pressure	45159701	11556	OWN	Bayer Report No. 75142 (EP)		



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		DATA MATRIX			
Date February 8, 2010			EPA Reg No./File Symbol 11556-131		Page 5 of 8
Applicant's/Registrant's Name & Address	Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201	Product CyLence® Ultra Insecticide Cattle Ear Tag			
Ingredient Cyano(4-fluoro-3-phenoxypheno Piperonyl Butoxcide – CAS # 5	yl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethyl 1-03-6	cyclopropanecarboxylat	e - CAS # 68359-37-5		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100 870.1200	TOXICOLOGY Acute oral toxicity, rat Acute dermal toxicity, rat	45640701	11556	OWN	Waived, see review dated 6/7/2002; secondary request in 90d PDCI Acceptable; see review dated 6/7/2002
870.1300	Acute inhalation toxicity, rat				Waived, see review dated 6/7/2002; secondary request in 90d PDCI
870.2400	Primary eye irritation, rabbit				Waived, see review dated 6/7/2002; secondary request in 90d PDCI
870.1300	Acute inhalation toxicity, rat				Waived, see review dated 6/7/2002; secondary request in 90d PDCI
870.2400	Primary eye irritation, rabbit				Waived, see review dated 6/7/2002; secondary request in 90d PDCI



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DATA MATRIX								
Date February 8, 2010 EPA Reg No./File Symbol 11556-131 Page 6 of 8								
Applicant's/Registrant's Name & Address Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201 Product CyLence® Ultra Insecticide Cattle Ear Tag								
Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5 Piperonyl Butoxcide - CAS # 51-03-6								
Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note								

870.2500	Primary dermal irritation, rabbit				Waived, see review dated 6/7/2002; secondary request in 90d PDCI
870.2500	Primary dermal irritation, rabbit				Waived, see review dated 6/7/2002; secondary request in 90d PDCI
870.6500	Dermal sensitization, guinea pig				Waived, see review dated 6/7/2002; secondary request in 90d PDCI
171-13	Analytical Reference Standard				Available upon request
171-3	Directions for Use		11556	OWN	Label, date of Draft submitted with this application
171-4(b)	Nature of Residue - Animal	137549 131506	3125 3125	PER	Miles Brochure No. 1223
171-4(d)	Analytical Method - Animal	4030502 137548	3125 3125	PER	Rprt No. 85883 Rprt No. 86232



DATA MATRIX							
Date February 8, 2010			EPA Reg No./File Symbol 11556-131		Page 7 of 8		
Applicant's/Registrant's Name & Address	Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201		Product CyLence® Ultra Insecticide Catt	tle Ear Tag	g		
Ingredient Cyano(4-fluoro-3-phenoxypheny Piperonyl Butoxcide – CAS # 51	d)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylc -03-6	yclopropanecarboxylate	- CAS # 68359-37-5				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note		

171-4(e)	Storage Stability	43533703	3125	PER	Rprt No. 94303
171-4(j)	Magnitude of Residue Meat/milk/poultry/egg	00131506 00137549	3125 3125	PER	Rprt No. 86045 and Rprt No. 86046, part of Brochure 1223
		41001621 43533702 43533701 43803001 41555702 41555703	3125 3125 3125 3125 3125 11556 11556	OWN OWN	Rprt No. 98505 Rprt No. 106628 Rprt No. 106629 Rprt No. 106977 Rprt No. 74050 Rprt No. 74051
171-5	Reduction of Residue	FAP No. 1F3923 FAP No. 9F3731 FAP No. 4F3046	11556 3125 3125	OWN PER PER	Petition No. 1F3923 Petition No. 9F3731 Petition No. 4F3046
171-6	Proposed Tolerance	FAP No. 1F3923 FAP No. 9F3731 FAP No. 4F3046	11556 3125 3125	OWN PER PER	Petition No. 1F3923 Petition No. 9F3731 Petition No. 4F3046
171-7	Support for Tolerance	FAP No. 1F3923 FAP No. 9F3731 FAP No. 4F3046	11556 3125 3125	OWN PER PER	Petition No. 1F3923 Petition No. 9F3731 Petition No. 4F304630



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DATA MATRIX							
Date February 8, 2010			EPA Reg No./File Symbol 11556-131		Page 8 of 8		
Applicant's/Registrant's Name & Address	Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201		Product CyLence® Ultra Insecticide Cattle Ear Tag				
Ingredient Cyano(4-fluoro-3-phenoxyphen Piperonyl Butoxcide – CAS # 5	/l)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylc -03-6	yclopropanecarboxylate	e - CAS # 68359-37-5				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note		

Signature North A. Billin Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs Date: 2/8/2010



		DATA MATRIX			
Date February 8, 2010			EPA Reg No./File Symbol 11556-131 Page 1 of 8		
Applicant's/Registrant's Name & Address	Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201		Product CyLence® Ultra Insecticide Cattle Ear Tag		
Ingredient Cyano(4-fluoro-3-phenoxypheno Piperonyl Butoxcide – CAS # 5	yl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethyl 1-03-6	cyclopropanecarboxyla	te - CAS # 68359-37-5		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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		DATA MATRIX			
Date February 8, 2010			EPA Reg No./File Symbol 11556-131		Page 2 of 8
Applicant's/Registrant's Name & Address	Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201		Product CyLence® Ultra Insecticide Cattle Ear Tag		
Ingredient Cyano(4-fluoro-3-phenoxypheny Piperonyl Butoxcide – CAS # 51	/l)methyl 3-(2,2-dichloroethenyl)-2,2-dimethyld 1-03-6	yclopropanecarboxylate	e - CAS # 68359-37-5		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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		DATA MATRIX			
Date February 8, 2010			EPA Reg No./File Symbol 11556-131		Page 3 of 8
Applicant's/Registrant's Name & Address	Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201		Product CyLence® Ultra Insecticide Cat	tle Ear Tag	9
Ingredient Cyano(4-fluoro-3-phenoxyphen Piperonyl Butoxcide CAS # 5	yl)methyl 3-(2,2-dichloroethenyl)-2,2-dimeth I-03-6	ylcyclopropanecarboxylat	e - CAS # 68359-37-5		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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1		DATA MATRIX			
Date February 8, 2010			EPA Reg No./File Symbol 11556-131		Page 4 of 8
Applicant's/Registrant's Name & Address	Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201		Product CyLence® Ultra Insecticide Cattle Ear Tag		9
Ingredient Cyano(4-fluoro-3-phenoxyphen Piperonyl Butoxcide – CAS # 5	yl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethyld 1-03-6	cyclopropanecarboxylate	e - CAS # 68359-37-5		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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		DATA MATRIX			
Date February 8, 2010		-	EPA Reg No./File Symbol 11556-131		Page 5 of 8
Applicant's/Registrant's Name & Address	Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201		Product CyLence® Ultra Insecticide Cattle Ear Tag		
Ingredient Cyano(4-fluoro-3-phenoxyphen Piperonyl Butoxcide – CAS # 5	yl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethyld 1-03-6	yciopropanecarboxylat	e - CAS # 68359-37-5		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			11556	OWN	



		DATA MATRIX			
Date February 8, 2010			EPA Reg No./File Symbol	EPA Reg No./File Symbol 11556-131 Page 6 of	
pplicant's/Registrant's Name & Address Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201		Product CyLence® Ultra Insecticide Cattle Ear Tag			
ngredient Cyano(4-fluoro-3-phenoxyphen Piperonyl Butoxcide – CAS # 5	nyl)methyl 3-(2,2-dichloroethenyl)-2,2-dim i1-03-6	nethylcyclopropanecarboxyl	ate - CAS # 68359-37-5		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			11556	OWN	
			11556 3125 3125	OWN PER	



Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and .025 hours per response for information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to the address.

DATA MATRIX Date February 8, 2010 EPA Reg No./File Symbol 11556-131 Page 7 of 8 Bayer Healthcare LLC Animal Health Division Applicant's/Registrant's Name & Address Product CyLence® Ultra Insecticide Cattle Ear Tag P.O. Box 390 Shawnee Mission, KS 66201 Ingredient Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate - CAS # 68359-37-5 Piperonyl Butoxcide - CAS # 51-03-6 Guideline Study Name MRID Number Guideline Reference Number Submitter Status Note

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	11556 3125 3125	OWN PER PER
	11556 3125 3125	OWN PER PER
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		DATA MATRIX				
Date February 8, 2010			EPA Reg No./File Symbol	11556-131		Page 8 of 8
Applicant's/Registrant's Name & Address	ddress Bayer Healthcare LLC Product CyLence® Ultra Insecticide Cattle Ear Tag Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201					
ngradient Cyano/4-fluora-3-phonoxyphon	nyl)methyl 3-(2,2-dichloroethenyl)-2,2-dim	ethylcyclopropanecarboxy	ate - CAS # 68359-37-5			
Ingredient Cyano(4-fluoro-3-phenoxyphen Piperonyl Butoxcide – CAS # 5		, .,, ,				
		MRID Number	Submitter		Status	Note

CyLence Ultra Tag.txt PDMS Database Web Search - NPIRSAll Available Data

Date of Search: 02/08/10 Time of Search: 14:07

Last Search: Administrative Numbers: 11556-131

Number of Citations Selected: 8

45159700 Bayer Corporation (2000) Submission of Product Chemistry Data in Support of the Application for Registration of Cutter Ultra

Insecticide Ear Tag. Transmittal of 1 Study.

Trade Secret Status: 0

Submitter: BAYER HEALTHCARE LLC

Submitter No. Submission Date Administrative No. Accession No. 07/03/00 451597 00 011556 011556-131

NO laboratory records for MRID: 45159700

*** Chemistry Indexing ***
SUBSTANCE CLASS: Single

FORMULATION: Not Formulated Pesticide

Piperonyl butoxide (67501)

FORMULATION: Not Formulated Pesticide SUBSTANCE CLASS: Single

beta-cyfluthrin (118831)

*** Subject Indexing ***

ROOT DT: 05

Product/Manufacturing Chemistry & Analysis

CONTENT CATEGORY: Transmittal Documents

*** Key Author Information ***
DOCUMENT TYPE: Submittal Document

PAGE COUNT: 00001

NO related Documents for MRID: 45159700

45159701 Rose, J. (1999) Report for the Chemistry Evaluation of M779 Cattle Ear Tags (Containing 8% Beta Cyfluthrin and 20% Piperonyl Butoxide): Lab Project Number: M779S03: M779R03: M779P03. Unpublished study prepared by Ecto Development Corporation. 42 p. {OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.7300, 830.6314, 830.6320}

Trade Secret Status: CBI Document, Confidential A

Submitter: BAYER HEALTHCARE LLC

Submitter No. Submission Date Administrative No. Accession No.

451597 01 011556 07/03/00 011556-131

Laboratory No.: ECTO DEVELOPMENT CORP 067505

Lab Project No.: M779S03*

Laboratory No.: *00000 LABORATORY NAME NOT AVAILABLE

Lab Project No.: M779R03* M779P03*

Laboratory No.: 011556 BAYER HEALTHCARE LLC

Lab Project No.: SPONSOR* M779P03*

Page 1

CyLence Ultra Tag.txt

```
*** Chemistry Indexing ***
         SUBSTANCE CLASS: Single
                                            FORMULATION: Not Formulated Pesticide
            Piperonyl butoxide (67501)
                                            FORMULATION: Not Formulated Pesticide
         SUBSTANCE CLASS: Single
            beta-cyfluthrin (118831)
         *** Subject Indexing ***
         ROOT DT: 0505
            Physical/Chemical Characteristics
         GUIDELINE: 63-0
Reports of Multiple Physical/Chemical Characteristics
         CONTENT CATEGORY: Complete Primary Report -- Experimental Research
         ROOT DT: 052010
            Product Mfg - Beginning Materials & Mfg Process
         GUIDELINE: 61-2
         Product Identity - Beginning Materials & Manufacturing Process CONTENT CATEGORY: Complete Primary Report -- Experimental Research
         ROOT DT: 052020
            Product Mfg - Formation of Unintentional Ingred/Impurities
         GUIDELINE: 61-3
            Product Identity - Discussion of Formation of Impurities
         CONTENT CATEGORY: Complete Primary Report -- Experimental Research
         ROOT DT: 05202502
            Product Mfg - Preliminary Analysis
         GUIDELINE: 62-1
            Analysis of Ingredients - Preliminary Analysis of Product Samples
         CONTENT CATEGORY: Complete Primary Report -- Experimental Research
         ROOT DT: 05202504
            Product Mfg - Certification of Limits
         GUIDELINE: 62-2
         Analysis of Ingredients - Certification of Limits
CONTENT CATEGORY: Complete Primary Report -- Experimental Research
         ROOT DT: 05202506
            Product Mfg - Analytical Methods to Verify Limits
         GUIDELINE: 62-3
            Analysis of Ingredients - Analytical Methods to Verify Limits
         CONTENT CATEGORY: Complete Primary Report -- Experimental Research
         ROOT DT: 0530
            Composition of Pesticide Products
         GUIDELINE: 61-1
            Product Identity & Disclosure of Ingredients
         CONTENT CATEGORY: Complete Primary Report -- Experimental Research
         *** Key Author Information ***
         DOCUMENT TYPE: Unpublished Monograph
         AUTHOR: ROSE/J*
         TITLE: REPORT/FOR/THE/CHEMI
                01/01/99
         DATE:
                                PAGE COUNT: 00042
         NO related Documents for MRID: 45159701
45444600 Bayer Corporation (2001) Submission of Toxicity Data in Support
            of the Application for Registration of Cutter Ultra Cattle Ear
            Tag. Transmittal of 1 Study.
```

Page 2

141

CyLence Ultra Tag.txt

Trade Secret Status:

Submitter: BAYER HEALTHCARE LLC

Submitter No. Submission Date Administrative No. Accession No. 454446 00 011556 06/11/01 011556-131

NO laboratory records for MRID: 45444600

*** Chemistry Indexing ***

SUBSTANCE CLASS: Single FORMULATION: Not Identified

beta-cyfluthrin (118831)

SUBSTANCE CLASS: Single FORMULATION: Not Formulated Pesticide

Piperonyl butoxide (67501)

*** Subject Indexing ***

ROOT DT: 40

Pesticide Effects on Non-target Animals (Including Man)

CONTENT CATEGORY: Transmittal Documents

*** Key Author Information ***
DOCUMENT TYPE: Submittal Document

PAGE COUNT: 00001

NO related Documents for MRID: 45444600

45444601 Johnson, K. (2001) M779 Cattle Ear Tag An Acute Dermal LD50 Study in the Rat: Revised Report: Lab Project Number: 01-A22-DU: 75303. Unpublished study prepared by Bayer Corporation. 46 p. {OPPTS 870.1200}

Trade Secret Status: Document Contains CBI

Submitter: BAYER HEALTHCARE LLC

Submitter No. Submission Date Administrative No. Accession No. 454446 01 011556-131

011556 06/11/01

Laboratory No.: 959961 MOBAY CHEMICAL CORP.

Lab Project No.: 01/A22/DU*

Laboratory No.: *00000 LABORATORY NAME NOT AVAILABLE

Lab Project No.: 75303*

Laboratory No.: 011556 BAYER HEALTHCARE LLC

Lab Project No.: SPONSOR*

*** Chemistry Indexing ***

SUBSTANCE CLASS: Single FORMULATION: Not Identified

beta-cyfluthrin (118831)

FORMULATION: Not Identified SUBSTANCE CLASS: Single

Piperonyl butoxide (67501)

*** Subject Indexing *** ROOT DT: 40050510

Acute Exposure - Dermal

GUIDELINE: 81-2

Acute Tox & Irritation - Acute Dermal Toxicity Page 3

CyLence Ultra Tag.txt

Lab Project No.: SPONSOR*

*** Chemistry Indexing ***
SUBSTANCE CLASS: Single

FORMULATION: Not Identified

Piperonyl butoxide (67501)

SUBSTANCE CLASS: Single

beta-cyfluthrin (118831)

*** Subject Indexing ***

ROOT DT: 40050510

Acute Exposure - Dermal

GUIDELINE: 81-2

Acute Tox & Irritation - Acute Dermal Toxicity

CONTENT CATEGORY: Incomplete or Summarized -- Experimental Research TEST ORGANISM: Laboratory Mammals - Rat

FORMULATION: Not Identified

GUIDELINE: 870.1200 Acute Dermal Toxicity

*** Key Author Information ***
DOCUMENT TYPE: Unpublished Monograph

AUTHOR: JOHNSON/K*

TITLE: M779/CATTLE/EAR/TAG/

PAGE COUNT: 00050 02 DATE:

NO related Documents for MRID: 45640701

47850900 Bayer HealthCare, LLC. (2009) Submission of Product Chemistry Data in Support of the Registration of CyLence Ultra Insecticide Cattle Ear Tag. Transmittal of 1 Study.

Trade Secret Status: Document Contains CBI

Submitter: BAYER HEALTHCARE LLC

Submitter No. Submission Date Accession No. 09/15/09 478509 00 011556

Administrative No: 011556-131

NO laboratory records for MRID: 47850900

*** Chemistry Indexing ***

SUBSTANCE CLASS: Single Piperonyl butoxide (67501) FORMULATION: Not Formulated Pesticide

SUBSTANCE CLASS: Single FORMULATION: Not Formulated Pesticide beta-cyfluthrin (118831)

*** Subject Indexing ***

ROOT DT: 05

Product/Manufacturing Chemistry & Analysis

CONTENT CATEGORY: Transmittal Documents

*** Key Author Information *** DOCUMENT TYPE: Submittal Document

AUTHOR: BAYER/HEALTHCARE/LL

NO related Documents for MRID: 47850900

47850901 Rose, J. (2001) Report for Stability Evaluation of "M779 Cattle Ear Page 5

CyLence Ultra Tag.txt Tags" (Containing 8% Beta Cyfluthrin and 20% Piperonyl Butoxide). Project Number: 33716, M779S02, M779R02. Unpublished study prepared by Ecto Development Corporation. 17 p.

Trade Secret Status: Document Contains CBI

Submitter: BAYER HEALTHCARE LLC

Submitter No. Submission Date Accession No. 09/15/09 478509 01 011556

Administrative No: 011556-131

Laboratory No.: 011556 BAYER HEALTHCARE LLC

> 067505 ECTO DEVELOPMENT CORP

Lab Project No.: 33716 M779R02 M779S02

*** Chemistry Indexing ***
SUBSTANCE CLASS: Single

FORMULATION: Not Formulated Pesticide

Piperonyl butoxide (67501)

SUBSTANCE CLASS: Single FORMULATION: Not Formulated Pesticide

beta-cyfluthrin (118831)

*** Subject Indexing ***
ROOT DT: 0525

Storage Stability/Shelf Life GUIDELINE: 830.6317

Storage Stability

CONTENT CATEGORY: Complete Primary Report -- Experimental Research

*** Key Author Information ***
DOCUMENT TYPE: Unpublished Monograph

AUTHOR: ROSE/J

TITLE: Report for Stability DATE: 08/27/01

NO related Documents for MRID: 47850901

*** END OF OUTPUT ***

OCopyright 1998-2010 Purdue University. All rights reserved.

Date:	3/09		
MEMORAN	<u>iDUM</u>		
SUBJECT:	Request for review of Data Waive Submitted in Response to the Prod		
	RED (name): PBO	Case	e#: <u>2525</u>
TO:	PRB Science Team	PC,	067501
FROM:	Stokes	CRM	

Please review the attached request(s) for data waivers and/or time extension(s). Please give recommendations for approval, disapproval or other action(s) with rationale/reasons as appropriate.

EDAD NI-	CINH	T	A1/	EDA Des No	CLN#	т	A1/
EPA Reg. No.	GLN#	T	Approval/	EPA Reg. No.	GLN#	T	Approval/
		W	Disapproval/			W	Disapproval/
11 == 7		*	Other Action	7		•	Other Action
14556-131	870.1100	W	approved	(cat 3)			
	1300	W	11				
	,2400	W	61				
	. 2500	W	U				
	. 2600	11	disapprove	* # see	note bei	(אדט)	
			7/1	J			
					· · · · · · · · · · · · · · · · · · ·		

T – Request for Time extension W - Request for Data Waiver

* information potential of	on sensitizing components
needed.	

needed.

* Lee amended waver rejuest result

for \$70,2600 in email dated.

Autimale:

See sty support that earn in social trineits are

sensitizing

145 1-15-10

DATA PACKAGE BEAN SHEET

Date: 05-Oct-2009 Page 1 of 2

Decision #: 420374

DP #: (370264) NON PRIA

Parent DP #:

Submission #: 858087

* * * Registration Information * * *

Registration:	11556-131 - CU	TTER ULTRA INSE	CTICIDE CATTL	E EAR TAG	
Company:	11556 - BAYER HE	ALTHCARE LLC			
Risk Manager:	RM 13 - Richard Ge	bken - (703) 305-6701 Re	oom# PY1 S-7237		
Manager Reviewer:	Olga Odiott OODIO	П			
Sent Date:	15-Sep-2009	Calculated D	Due Date: 03-Jan-201	10	Edited Due Date:
Type of Registration:	Product Registration	- Section 3			
Action Desc:	(570) CONDITIONA	L REGISTRATION FOLL	OW-UP;DATA REQ	UIRED;REQUIRES	RD REVII
Ingredients:	067501, Piperonyl b	utoxide(20%)		'	
	118831, beta-cyflutt	rrin(8%)			
	Yes ● No	D	ge Information		Due Back:
	118831, beta-cyflutt				
DP Title:					
CSF Included:	○ Yes ● No	Label Included:	Yes No F	Parent DP #:	
Assigned T	o	Date In	Date Ou	ıt	
Organization: RD / T	TRB			Last Possible	Science Due Date: 25-Oct-2009
Team Name: CHEM	Л				Science Due Date:
eviewer Name:				Sub Data I	Package Due Date:
ntractor Name:					

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Please review attached storage stability data submitted to comply with conditional registration requirements. Thanks, Olga

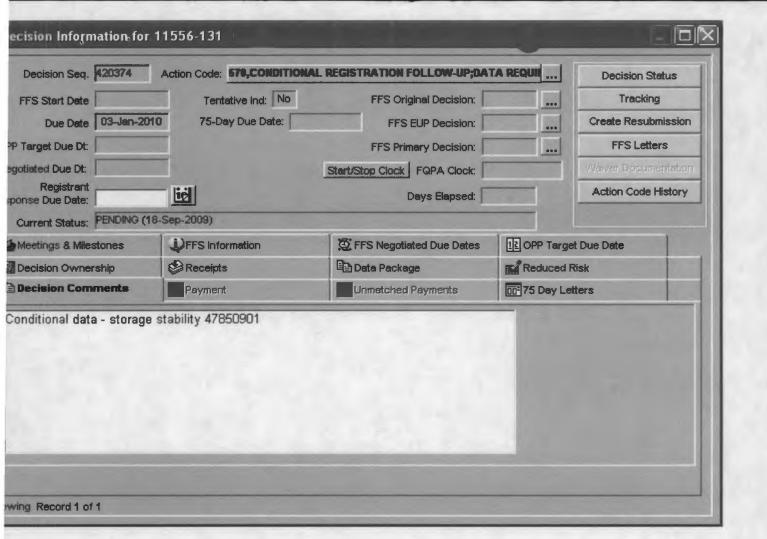
ntra

Page 2

* * * Studies Sent for Review * * * Decision#: (420374) (370264)

Guideline **MRID Status** Citation Reference RID 0901

Rose, J. (2001) Report for Stability Evaluation of "M779 Cattle Ear 830.6317/Storage stability of product Tags" (Containing 8% Beta Cyfluthrin and 20% Piperonyl Butoxide). Project Number: 33716, M779S02, M779R02. Unpublished study prepared by Ecto Development Corporation. 17 p.

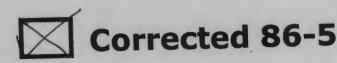


This package of rejected data
has been corrected.

Please resubmit through the
86-5 screen for MRID Number
Assignment.

Thank you,

RD Completeness Check Team





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

September 15, 2009

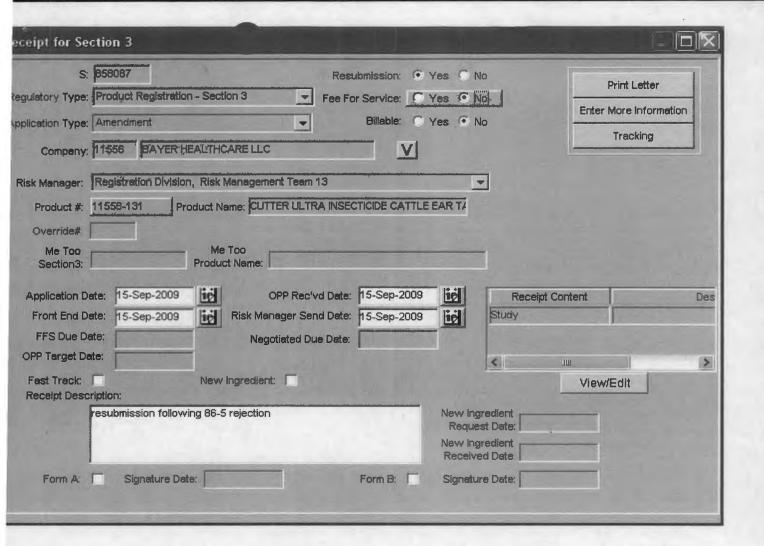
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

BAYER HEALTHCARE LLC ANIMAL HEALTH DIVISION PO Box 390 SHAWNEE MISSION, KS 66201-0390

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 15-SEP-09. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



Bayer HealthCare Animal Health



Via Federal Express - Express Saver

August 10, 2009

Document Processing Desk (Additional Data)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention:

Ms. Kimberly Nesci/PM13, Registration Division (7505P)

Subject:

CyLence Ultra Insecticide Cattle Ear Tag

(EPA Reg. No. 11556-131) Submission of Storage Stability Bayer HealthCare LLC Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390

Dear Ms. Nesci:

In support of the continued registration of the subject product, please find enclosed the report entitled, Report for the Stability Evaluation of "M779 Cattle Ear Tags" (Containing 8% Beta Cyfluthrin and 20% Piperonyl Butoxide).

If you need further information, please do not hesitate to call (913-268-2751).

Sincerely

Douglas A. Spilker. Ph. D.

Manager, EPA Regulatory Affairs

Doug.Spilker.b@Bayer.com

DAS/lt

Enclosures: Transmittal Document with Report ID No. 33716 (3 copies)

Transmittal Document

1. Name and Address of Submitter

Bayer HealthCare LLC

Animal Health Division

Box 390

Shawnee Mission, Kansas 66201-0390

Douglas A. Spilker, Ph.D.

Manager, EPA Regulatory Affairs

(913) 268-2751

2. Regulatory Action in Which this Package is Submitted

Submission of storage stability (830.6317)

3. <u>Transmittal Date</u>

August 10, 2009

4. List of Submitted Studies:

MRID No. Volume

47850901

- Report for the Stability Evaluation of "M779 Cattle Ear Tags" (Containing 8% Beta Cyfluthrin and 20% Piperonyl Butoxide), OPPT 830.6317, Report ID No. 33716, Rose, J., 17 pp.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

August 17, 2009

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

BAYER HEALTHCARE LLC ANIMAL HEALTH DIVISION PO Box 390 SHAWNEE MISSION, KS 66201-0390

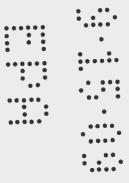
Report of Analysis for Compliance with PR Notice 86-5

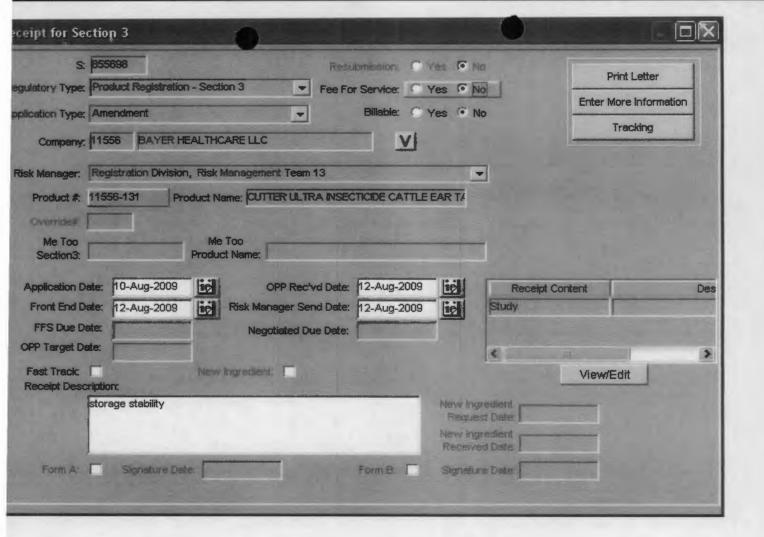
Thank you for your submittal of 12-AUG-09. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studes, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected Study [01]:

* You must include <u>one</u> of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.





conditional

Memorandum

Date:	6/18/09	_		
To:	m 13	, Regu	latory	Manager
From:	Information Service	es Branch,	, ITRM	D
indicatio	or receipt of this data on that MRIDs for the sted to OPPIN.			
from the	expect that it will be above date before e in OPPIN.	* *		
	ou have any questio ontact Teresa Down		^	cess,
This is a	: □ fully accept □ partially acc □ rejected sub	cepted sub		n.

Bayer HealthCare



Via Federal Express – Express Saver

August 10, 2009

Document Processing Desk (Additional Data) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attention:

Ms. Kimberly Nesci/PM13, Registration Division (7505P)

Subject:

CyLence Ultra Insecticide Cattle Ear Tag

(EPA Reg. No. 11556-131) Submission of Storage Stability Bayer HealthCare LLC Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390

Dear Ms. Nesci:

In support of the continued registration of the subject product, please find enclosed the report entitled, Report for the Stability Evaluation of "M779 Cattle Ear Tags" (Containing 8% Beta Cyfluthrin and 20% Piperonyl Butoxide).

If you need further information, please do not hesitate to call (913-268-2751).

Sincerely

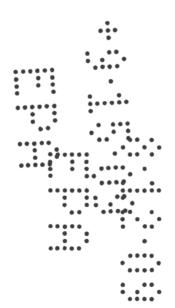
Douglas A. Spilker. Pl. D.

Manager, EPA Regulatory Affairs

Doug.Spilker.b@Bayer.com

DAS/lt

Enclosures: Transmittal Document with Report ID No. 33716 (3 copies)



Transmittal Document

1. Name and Address of Submitter

Bayer HealthCare LLC Animal Health Division

Box 390

Shawnee Mission, Kansas 66201-0390

Douglas A. Spilker, Ph.D.

Manager, EPA Regulatory Affairs

(913) 268-2751

2. Regulatory Action in Which this Package is Submitted

Submission of storage stability (830.6317)

3. Transmittal Date

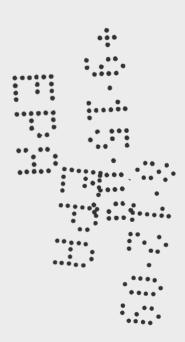
August 10, 2009

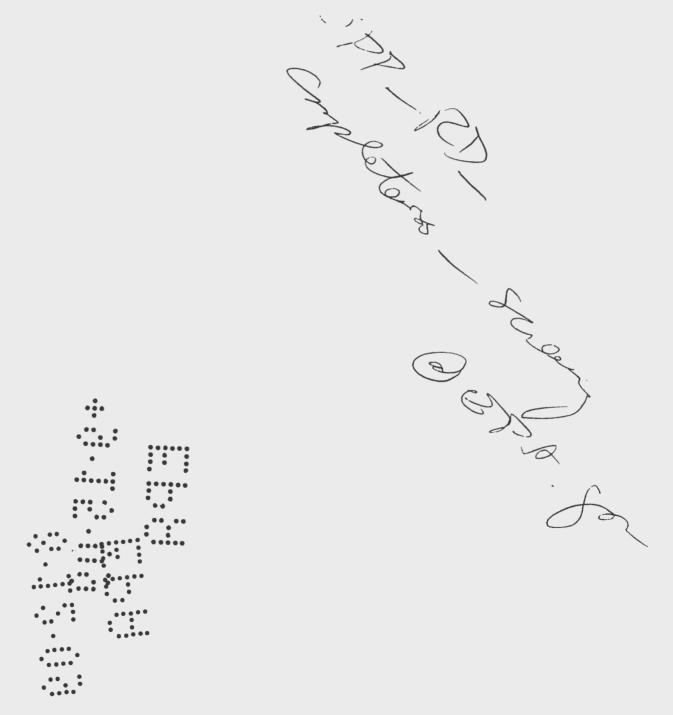
4. List of Submitted Studies:

MRID No. Volume

Reject (01)

- Report for the Stability Evaluation of "M779 Cattle Ear Tags" (Containing 8% Beta Cyfluthrin and 20% Piperonyl Butoxide), OPPT 830.6317, Report ID No. 33716, Rose, J., 17 pp.





Generic and Product Specific Data Call-In Notice
CyLence Ultra Insecticide Cattle Ear Tag (EPA Reg. No. 11556-131)
Ingredient Name: Piperonyl Butoxide – Case #2525

Request for Waivers for Certain Acute Toxicity Study Requirements

The acute toxicity studies normally associated with a formulated product were not conducted because they are not practical or necessary for a cattle ear tag. In explanation, the physical nature of the product, which is a plastic ear tag, is not a practical test article for the conduct of: a) acute oral toxicity, b) acute inhalation toxicity, c) primary eye irritation, d) primary dermal irritation, or e) dermal sensitization. These aforementioned studies were waived when the original registration was granted (see EPA memoranda, dated 07 June 2002 and 13 Sept 2001; both attached). An acceptable study (MRID 45640701) is on file with the Agency for the acute dermal toxicity (870.1200) data requirement.

We therefore request the respective waivers for the following data requirements for the subject end-use product containing Piperonyl Butoxide:

- a) acute oral toxicity (870.1100)
- b) acute inhalation toxicity (870.1300)
- c) primary eye irritation (870.2400)
- d) primary dermal irritation (870.2500)
- e) dermal sensitization (870.2600)

Attachments:

- 1. EPA memoranda, dated 07 June 2002
- 2. EPA memoranda, dated 13 Sept 2001



PBO Waiver request for DCI.doc

Bayer HealthCare Animal Health



Via Federal Express

September 10, 2009

Document Processing Desk (DCI/SRRD)
Katherine St. Clair
Office of Pesticide Programs (7508P)
U.S. Environmental Protection Agency
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202

Subject: Generic and Product Specific Data Call-In Notice

Official Product Name: CyLence Ultra Insecticide Cattle Ear Tag

EPA Reg No.: 11556-131

Response to Data Call-In Letter Dated June 16, 2009 Ingredient Name: Piperonyl Butoxide – Case #2525

Dear Katherine St. Clair:

This is in response to the subject DCI Letter from EPA (Richard P. Keigwin) dated June 16, 2009, concerning the reregistration of the subject product.

- 1. Cover letter
- 2. Richard P. Keigwin letter dated June 16, 2009 (Pages 1 & 16 only)
- 3. EPA Memorandum, dated June 16, 2009 (Page 1)
- 4. "Data Call-In Response" Piperonyl Butoxide

Nogla A. Spiller

- 5. "Requirements Status and Registrant's Response"
- 6. Request for Waivers of certain acute toxicity studies

If there are any questions concerning this response, please contact me by phone (913-268-2751) or e-mail (doug.spilker.b@bayer.com).

Sincerely,

Douglas A. Spilker. Ph. D.

Manager, EPA Regulatory Affairs

Doug.Spilker.b@Bayer.com

DAS/lt

cc (with attachment): Julia Stokes, Chemical Review Manager

Bayer HealthCare LLC Animal Health P.O. Box 390 Shawnee Mission, KS 66201-0390

V 92509

Bayer HealthCare Animal Health

BAYER

Bayer HealthCare LLC

Shawnee Mission, KS 66201-0390

Animal Health P.O. Box 390

Via Federal Express

September 10, 2009

Document Processing Desk (DCI/SRRD)
Katherine St. Clair
Office of Pesticide Programs (7508P)
U.S. Environmental Protection Agency
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202

Subject: Generic and Product Specific Data Call-In Notice

Official Product Name: CyLence Ultra Insecticide Cattle Ear Tag

EPA Reg No.: 11556-131

Response to Data Call-In Letter Dated June 16, 2009 Ingredient Name: Piperonyl Butoxide – Case #2525

Dear Katherine St. Clair:

This is in response to the subject DCI Letter from EPA (Richard P. Keigwin) dated June 16, 2009, concerning the reregistration of the subject product.

- 1. Cover letter
- 2. Richard P. Keigwin letter dated June 16, 2009 (Pages 1 & 16 only)
- 3. EPA Memorandum, dated June 16, 2009 (Page 1)
- 4. "Data Call-In Response" Piperonyl Butoxide

Nogla A. Spiller

- 5. "Requirements Status and Registrant's Response"
- 6. Request for Waivers of certain acute toxicity studies

If there are any questions concerning this response, please contact me by phone (913-268-2751) or e-mail (doug.spilker.b@bayer.com).

Sincerely,

Douglas A. Spilker. Ph. D.

Manager, EPA Regulatory Affairs

Doug.Spilker.b@Bayer.com

DAS/lt

cc (with attachment): Julia Stokes, Chemical Review Manager

United States Environmental Protection Agency Washington, D.C. 20460

DATA CALL-IN RESPONSE

OMB Approval 2070-0107 OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary. 1. Company Name and Address 2. Case # and Name 3. Date and Type of DCI and Number BAYER HEALTHCARE LLC 2525 Piperonyl butoxide 19-May-2009 PO Box 390 Chemical # and Name 067501 PRODUCT SPECIFIC Piperonyl butoxide SHAWNEE MISSION, KS 662010390 ID# PDCI-067501-26956 6. Generic Data 7. Product Specific Data PΑ 5. I wish to uct cancel this product regis-. ..gistration 6a. I am claiming a Generic 6b. I agree to satisfy Generic 7a. My product is an MUP and 7b. My product is an EUP and I agree to satisfy the MUP tration volun-Data Exemption because I Data requirements as indicated I agree to satisfy the EUP tarily obtain the active ingredient on the attached form entitled requirements on the attached requirements on the attached from the source EPA regis-"Requirements Status and form entitled "Requirements form entitled "Requirements tration number listed below. Registrant's Response." Status and Registrant's Status and Registrant's Response." Response." 11556-131 N.A. N.A. Yes 8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any 163

8. Certification I certify that the statements made on this form and all attachments are true, according to knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Municipal EA+

Reg. Affaires

10 Sept 2009

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0107 OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1 Company Name and	d Address	2. Case # and Name						3 Date and Type of DCI a	nd Number		
1. Company Name and Address								Date and Type of DCI and Number			
BAYER HEALTHCARE LLC		2525 Piperonyl butoxide						19-May-2009			
PO Box 390	SION KS 662010390							PRODUCT SPECIFIC			
SHAWNEE MISSION, KS 662010390		EPA Reg. No. 11556-131						ID # PDCI-067501-26956			
' Guideline 5. Study Title irement				P R Progre O Repo			6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrar Response	
ber									(Months)		
			COL	1	2	3					
	Product Chemistry Data Requirement	ts (Conventional	<u> </u>								
330.1550	Product Identity and composition	(40)					A, B, C, D, E, F, G, H, J, K, L, M, N, O	, I, TGAI/MP/EP	8	6	
330.1600	Description of materials used to produc	e the product (42)					A, B, C, D, E, F, G, H, J, K, L, M, N, O	, I, TGAI/MP/EP	8	6	
330.1620	Description of production process	(43)					A, B, C, D, E, F, G, H, J, K, L, M, N, O	, I, TGAI	8	8	
330.1650	Description of formulation process	(44)					A, B, C, D, E, F, G, H, J, K, L, M, N, O	, I, MP/EP	8	6	
330.1670	Discussion of formation of impurities	(45)					A, B, C, D, E, F, G, H, J, K, L, M, N, O		8	6	
700	Preliminary analysis	(1 ,2 ,41)					A, B, C, D, E, F, G, H, J, K, L, M, N, O	, I, TGAI	8	8	
330.1750	Certified limits	(46)					A, B, C, D, E, F, G, H, J, K, L, M, N, O	, I, TGAI/MP/EP	8	6	
330.1800	Enforcement analytical method	(47)					A, B, C, D, E, F, G, H, J, K, L, M, N, O	, I, TGAI/MP/EP	8	6	
830.6302	Color	(3)					A, B, C, D, E, F, G, H, J, K, L, M, N, O	, I, TGAI/MP/EP	8	6	
330.6303	Physical state	(4)					A, B, C, D, E, F, G, H, J, K, L, M, N, O	, I, TGAI/MP/EP	8	6	
330.6304	Odor	(5)					A, B, C, D, E, F, G, H, J, K, L, M, N, O	, I, TGAI/MP/EP	8	6	
10. Certification I ce	ertify that the statements made on this form an eading statement may be punishable by fine in	sall attachments are true.	CCUL	ate. a	and o	amo	Lete. I acknowledge that a	any 11. Date	Sept 20	-164	

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0107 OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address BAYER HEALTHCARE LLC PO Box 390 SHAWNEE MISSION, KS 662010390		2. Case # and Name 2525 Piperonyl butoxide EPA Reg. No. 11556-131					Date and Type of DCI and N 19-May-2009 PRODUCT SPECIFIC ID # PDCI-067501-2695		
4. Guideline Requirement Number	5. Study Title		PROTOC	Progress Reports		6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			L	1 2	3				
830.6313	Stability to sunlight, normal and elevated temperatures, metals, and metal ions	(6 ,7 ,48)	П			A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	S
830.6314	Oxidizing or reducing action	(8)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	6
830.6315	Flammability	(9)				A, B, C, D, E, F, G, H, I J, K, L, M, N, O	MP/EP	8	8
830.6316	Explodability	(10)		1		A, B, C, D, E, F, G, H, I J, K, L, M, N, O	MP/EP	8	8
830.6317	Storage stability of product	(49)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	16	6
830.6319	Miscibility .	(11)		II.		A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	8
830.6320	Corrosion characteristics	(50)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	16	6
830.6321	Dielectric breakdown voltage	(12)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	8
830.7000	pH of water solutions or suspensions	(13 ,14)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	8
830.7050	UV/Visible absorption					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	8
830.7100	Viscosity	(15)					MP/EP	8	. 8
830.7200	Melting point/melting range	(16 ,17)				A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI		8 65

United States Environmental Protection Agency Washington, D.C. 20460

<u>a</u>

OMB Approval 2070-0107 OMB Approval 2070-0057

166

REOUIREMENTS STATUS AND REGISTRANT'S RESPONSE INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary. 1. Company Name and Address 2. Case # and Name 3. Date and Type of DCI and Number **BAYER HEALTHCARE LLC** 2525 Piperonyl butoxide 19-May-2009 PO Box 390 PRODUCT SPECIFIC SHAWNEE MISSION, KS 662010390 ID # PDCI-067501-26956 EPA Reg. No. 11556-131 Guideline 6. Use 7. Test 8. Time 9. Registrant 5. Study Title **Progress** Pattern Frame Response irement Substance 0 Reports (Months) per 0 2 Boiling point/boiling range A. B. C. D. E. F. G. H. I. TGAL 830,7220 (18.19)8 J, K, L, M, N, O 6 A, B, C, D, E, F, G, H, I, TGAI/MP/EP Density/relative density (20, 21)830.7300 J, K, L, M, N, O A, B, C, D, E, F, G, H, I, TGAI or PAI 830.7370 Dissociation constant in water (22, 23)8 J. K. L. M. N. O A. B. C. D. E. F. G. H. I. TGAI/PAI Partition coefficient (n-octanol/water), shake flask 8 830.7550 (24)method J, K, L, M, N, O A, B, C, D, E, F, G, H, I, TGAI/PAI Partition coefficient (n-octanol/water), estimation by 830.7570 8 liquid chromatography J. K. L. M. N. O A, B, C, D, E, F, G, H, I, TGAI or PAI Water solubility: Column elution method, shake flask (26) 8 830.7840 method J. K. L. M. N. O A, B, C, D, E, F, G, H, I, TGAI or PAI Water solubility, generator column method (27)860 g J, K, L, M, N, O A, B, C, D, E, F, G, H, I, TGAI or PAI Vapor pressure (28.29)830.7950 J, K, L, M, N, O Foxicology Data Requirements (Conventional Chemical) Acute Oral Toxicity (30,51)A, B, C, D, E, F, G, H, I, TGAI, EP, dilute EP? 870.1100 J. K, L, M, N, O A, B, C, D, E, F, G, H, I, TGAI,EP, dilute EP? Acute dermal toxicity (31, 32, 52)870,1200 J, K, L, M, N, O (33)A, B, C, D, E, F, G, H, I, TGAI & EP 870.1300

J, K, L, M, N, O

United States Environmental Protection

Agency Washington, D.C. 20460

OMB Approval 2070-0107 OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

1. Company Name and Address BAYER HEALTHCARE LLC PO Box 390 SHAWNEE MISSION, KS 662010390			2525 Piperonyl butoxide EPA Reg. No. 11556-131				3. Date and Type of DCI and Number 19-May-2009 PRODUCT SPECIFIC ID # PDCI-067501-26956			
4. Guideline Requirement Number	5. Study Title		0 0 0 0	Progre	ess	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registral Response	
			O L 1	2	3					
870.2400	Acute eye imitation	(34)				A, B, C, D, E, F, G, H, I J, K, L, M, N, O	TGAI & EP	8	7	
870.2500	Acute dermal irritation	(35 ,36)				A, B, C, D, E, F, G, H, I J, K, L, M, N, O	TGAI & EP	8	7	
870.2600	Skin sensitization	(37 ,38)		100		A, B, C, D, E, F, G, H, I J, K, L, M, N, O	TGAI & EP	8	7	
870.7200	Companion animal safety	(39)				A, B, C, D, E, F, G, H, I J, K, L, M, N, O	CHOICE	8	8	
									0/	
									167	

MATERIAL TO BE ADDED TO JACKET

	R	EG#	11551	0-131	
Des	crip	tion:	Label	Revisions	
	che	ck all tha	t annly		
				accepted label	
		new C	SF		
·	X	notifica	ation		

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's			NOTIFICATION
Name:	Joyce Edwards	Date:	JUL 16 2008
	<i>O</i>	Division:	2)
Phone:	703 - 308 - 5479	Division:	ייייי



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUL 16 2008

Douglas A. Spilker, Ph.D. Manager, EPA Regulatory Affairs Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390

RE: Notification for Labe Revisions

EPA Reg. No.: 11556-131

Date of Submission: June 02, 2008

Dear Dr. Spilker:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated June 2, 2008, for the product CyLence Ultra Insecticide Cattle Ear Tag. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

Linda Arrington

Notifications & Minor Formulations Team Leader Registration Division (7505P)

Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUL 16 2008

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If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

Linda Arrington

Notifications & Minor Formulations Team Leader Registration Division (7505P)

Office of Pesticide Programs

Via Federal Express 06/02/2008

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Enclosure:

- Application for Pesticide Notification for CyLence Ultra Insecticide Cattle Ear Tag (EPA Reg. No. 11556-131)
- Five copies draft labeling
- One highlighted copy draft labeling



Please read instructions on reverse beautiful completing form.	Form Ap. Jd. OMB No. 2070-0060
United States Environmental Protection Ag Washington, DC 20460	ency Registration Amendment OPP Identifier Number Other
Application for	Pesticide - Section I
1. Company/Product Number 11556-131	2. EPA Product Manager George LaRocca 3. Proposed Classification
4. Company/Product (Name) CyLence Ultra Insecticide Cattle Ear Tag	PM# None Restricted
5. Name and Address of Applicant (Include ZIP Code) Bayer Healthcare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. NOTIFICATION Product Name JUL 16 2008
Se	ction - II
Amendment - Explain below. Resubmission in response to Agency letter dated	Final printed labels in response to Agency letter dated "Me Too" Application. Other - Explain below.
which has been modified only to change those items that fall un may be accomplished as Non-notifications. See attachment for for	label for CyLence Ultra Insecticide Cattle Ear Tag, dated May 28, 2008, der the scope of Pesticide Registration Notice (PRN) 98-10, PRN 97-5 or urther detail.
Se	ction - III
Packaging wgt. No. per Unit Packaging wgt. container	age wgt container Other (Specify)
3. Location of Net Contents Information 4. Size(s) Retail Cont	On Label
6. Manner in Which Label is Affixed to Product Lithograph Paper glued Stenciled	Other
Se	ction - IV
1. Contact Point (Complete items directly below for identification of inc	
Norme Douglas A. Spilker, Ph.D Title Management	ger, EPA Reg Affairs Telephone No. (Include Area Code) (913) 268-2751
Certification I certify that the statements I have made on this form and all atta I acknowledge that eny knowingly false or misleeding statement in both under applicable law.	chments thereto are true, accurate and complete. nay be punishable by fine or imprisonment of each of the complete. (Stamped)
100011-11-0	ger, EPA Regulatory Affairs
Douglas A. Spilker, Ph. D.	2 June 2008

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

White - EPA File Copy (original)

Yellow -Applicant Copy

ATTACHMENT FOR APPLICATION FOR PESTICIDE REGISTRATION June 2, 2008

CyLence® Ultra Insecticide Cattle Ear Tag (EPA Reg. No. 11556-131)

Enclosed with this Application for Pesticide Notification is a draft label for CyLence Ultra Insecticide Cattle Ear Tag, dated May 28, 2008, which has been modified only to change those items (see highlighted copy) that fall under the scope of Pesticide Registration Notice (PRN) 98-10, PRN 97-5 or may be accomplished as Non-notifications, and include:

- 1. Due to a change in the manufacturer's tradename of the applicator device for the ear tag, the applicator name for the ear tags has been changed in two places (pages 2 and 4) on the draft label
 - from: "For use with Allflex® Global Applicator with red pin and white clip"
 to: "For use with Allflex® Universal Total Tagger with red pin and black clip."
- 2. Delete the long chemical names in the ingredient statement in two places (pages 1 and 2) to only list common chemical name (Beta-cyfluthrin). This is allowed pursuant to PRN 97-5, and described in the Label Review Manual (Page 5-3).
- 3. Change of address to add more specific address (add P.O. Box number) in two places on the draft label (pages 1 and 2).
- 4. Change emergency telephone numbers; we are transitioning to another medical service, but the previous telephone numbers will remain in effect for some time.
- 5. Change the Warranty Statement as directed by the Agency to include the phrase "To the extent consistent with applicable law...."

6. Change establishment number (to another approved site) in two places on the draft-label (pages 1 and 5).

Page 1 of 2

Please note that we have opted not to change the storage and disposal statements at this time (pursuant to PR Notice 2007-4), awaiting further clarification from the Agency on these obviously non-refillable ear tag products.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been proposed for the labeling or the confidential statement of formula for this product. Bayer understands that it is a violation of 18 U.S. C. Sec. 1001 to willfully make any false statement to EPA. Bayer further understands that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and Bayer may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.



Page 2 of 2

or Label Modifications [Notification]

Date:

05/28/2008 08/07/2007

Supersedes:

Page 1 of 6

Pouch

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks for Up to Five Months.

		Percent By Weight
Active Ingredients	Beta-cyfluthrin	8%
	Piperonyl butoxide	20%
Other Ingredients		72%
Total		100%

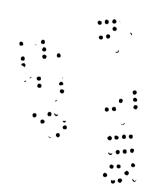
Keep Out of Reach of Children

CAUTION

See Box For Precautionary Statements

Net Contents: 10 Tags - 0.5 oz per tag

Manufactured for Bayer HealthCare, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201 U.S.A.



EPA Est. No. 67517-MO-1 EPA Reg. No. 11556-131

NOTIFICATION

JUL 16 2008

Date: Supersedes: 05/28/2008 08/07/2007

Page 2 of 6

Box (Front)

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For Use with Allflex Universal Total Tagger with red pin and black clip.

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks

- Effective Against Face Flies and Pyrethroid Susceptible Horn Flies for up to 5 months.
- Kills and Repels Face Flies mechanical vector of Moraxella bovis bacteria causing "pink eye" of cattle
- Synergized for extra performance

		Percent By Weight
Active Ingredients	Beta-cyfluthrin	8%
	Piperonyl Butoxide Technical	20%
Other Ingredients		72%
Total		100%

Keep Out of Reach of Children CAUTION

See Side Panel for Additional Precautionary Statements

Net Contents: 2 pouches of 10 tags each – 0.5 oz per tag

Bayer HealthCare, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201 U.S.A.

i. or Label Modifications [Notification]

Date:

05/28/2008 08/07/2007

Supersedes: Page 3 of 6

Box (Side Panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

May cause eye irritation. Harmful if swallowed, inhaled or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wear nonpermeable protective gloves when applying or removing tags. Wash thoroughly with soap and water after use and before eating, drinking or using tobacco.

FIRST AID

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If Swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If Inhaled:

- Move person to fresh air.
- If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment, call 1-800-422-9874. For customer service or to obtain product information, including MSDS, call 1-800-633-3796.

Environmental Hazards: This pesticide is toxic to fish. Do not contaminate water when disposing of used tags. Apply this product only as specified on the label.

Jr Label Modifications [Notification]

Date:

05/28/2008 08/07/2007

Supersedes: Page 4 of 6

Box (Back)

Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating).

All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. CyLence® Ultra Insecticide Ear Tags have been proven to be effective against face and horn flies for up to five months.

Use the Allflex Universal Total Tagger with the red pin and black clip to apply tags to cattle.

Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

(Illustration)	(Illustration)	(Illustration)	(Illustration)
Figure 1	Figure 2	Figure 3	Figure 4
Disinfect pliers prior to use. Place male button onto pin until it projects through the tip.	Slide tag under the clip of the pliers by depressing the lever.	Position tag in the center portion of the front side of the ear.	Apply the tag between the second and third rib cartilage.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. CyLence® Ultra Cattle Ear Tag contains the pyrethroid insecticide beta-cyfluthrin plus piperonyl butoxide, which is an insecticide synergist.

r Label Modifications [Notification]

Date:

05/28/2008 08/07/2007

Supersedes: Page 5 of 6

Box (Back)

Storage and Disposal:

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned stay out of smoke.

EPA Est. No. 67517-MO-1 EPA Reg. No. 11556-131

Jr Label Modifications [Notification] Reason to Issue:

Date:

05/28/2008 08/07/2007

Supersedes:

Page 6 of 6

Box (Side Panel)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. 11556-131
Send to SIG: check box This material is:
 □ New stamped-accepted label ✓ New CSF □ Notification □ Final Printed Label □ Other:
Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).
Reviewer's Name:
Phone: Division:
Date: 5 31/07

Ms. Mary McKinney Hunt Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390

Dear Ms. McKinney Hunt:

Subject: Amendment- Confidential Statement of Formula- alternate

Cutter Ultra Insecticide Cattle Ear Tag

EPA Registration Number 11556-131 Your submission dated April 3, 2007

The Agency has reviewed your alternate formulation dated

April 3, 2007 and it is acceptable.

Sincerely yours,

George T. LaRocca Product Manager (13) Insecticide Branch Registration Division (7505P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MAY 3 1 2007

Ms. Mary McKinney Hunt Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390

Dear Ms. McKinney Hunt:

Subject: Amendment- Confidential Statement of Formula- alternate

Cutter Ultra Insecticide Cattle Ear Tag

EPA Registration Number 11556-131 Your submission dated April 3, 2007

The Agency has reviewed your alternate formulation dated

April 3, 2007 and it is acceptable.

Sincerely yours,

George T. LaRocca Product Manager (13)

Let Ade Luis

Insecticide Branch

Registration Division (7505P)

Reg BK

DP BARCODE No.: <u>D339081</u> REG. No.: <u>11556-131</u> PRODUCT NAME: <u>Cutter Ultra Insecticide Cattle</u>

Ear Tag

DATE: 03 / MAY / 2007

SUBJECT: PRODUCT CHEMISTRY REVIEW OF TGAI/MP [] EP [X]

DP BARCODE No.: <u>D339081</u> REG. No.: <u>11556-131</u> PRODUCT NAME: <u>Cutter Ultra Insecticide Cattle ear tag</u>

COMPANY: Bayer Healthcare LLC

PCC: 118831; Decision No.: 378213; ACTION CODE: 345

FOOD USE [X]

INTEGRATED FORMULATION: Yes [] No []

FROM:

Shyam B. Mathur,

Product Chemistry Team Leader

Technical Review Branch/RD (7505P)

TO:

Linda DeLuise / George Larocca, RM 13

Insecticide Branch / RD (7505P)

INTRODUCTION

The registrant has submitted a CSF for alternate formulation (dated 04-03-07) to support the registration of the end use product Cutter Ultra Insecticide Cattle Ear tag. The Alternate CSF reflects a substitution of an inert ingredient (used as carrier) with other similar inert ingredient, no other changes are made with respect to the nominal concentration and certified limits of the active ingredient. TRB has been asked to determine the acceptability of the CSF for alternate formulation.

S18mester 05-03-07

SUMMARY OF FINDINGS

1. The end use product contains

- 2. The CSF for alternate formulation (dated 04-03-07) is filled out completely & correctly. The nominal concentration of the active ingredient concurs with the product label claim nominal concentration. The CSF is in compliance with PR Notice 91-2 and 40CFR152.43. The proposed certified limits for the active ingredient and the inert ingredients are in compliance with 40CFR§158.175(b) (2). All the food use inert ingredients present in the formulation are cleared by the Agency. The data submitted corresponding to guidelines 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the product chemistry data requirements of 40CFR§158.150 & 158.175 respectively.
- 3. The alternate CSF (dated 04-03-07) is substantially similar to the CSF for basic formulation (dated 03-08-02) in chemical composition and physical chemical properties.

CONCLUSIONS

TRB has evaluated the CSF for alternate formulation (dated 04-03-07) and has concluded that it is acceptable.

Bayer HealthCare Animal Health Division



April 3, 2007

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTENTION:

Mr. George LaRocca, PM 13

Registration Division

SUBJECT:

Amendment Application for Alternate CSF for 3 Products

CyLence Ultra Insecticide Cattle Ear Tag, 11556-131 Co-Ral Plus Insecticide Cattle Ear Tag, 11556-123 CheckMite+ Bee Hive Pest Control Strip, 11556-RGI Bayer HealthCare LLC Animal Health Division 12707 Shawnee Mission Parkway Shawnee Mission, KS 66216-1846

Dear Mr. LaRocca:

Enclosed please find the completed amendment applications for three Alternate Confidential Statements of Formula for the above subject products. The same action is being submitted for all three products.

Please note that Bayer is adding the same alternate proprietary inert ingredient component. (block 10), for each product.

Please contact me at <u>mary.hunt.b@bayer.com</u> or 913-268-2311 if you have any questions.

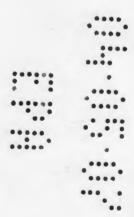
Respectfully,

BAYER HEALTHCARE LLC ANIMAL HEALTH DIVISION

Many McKinney Hunt

Mary McKinney Hunt Regulatory Specialist

encl: Amendment application packages (3 products)



Bayer HealthCare Animal Health Division

B A BAYER E R

April 3, 2007

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTENTION:

Mr. George LaRocca, PM 13

Registration Division

SUBJECT:

Amendment Application for Alternate CSF

CyLence Ultra Insecticide Cattle Ear Tag, 11556-131

Dear Mr. LaRocca:

Please find enclosed, for the Agency's review and approval, the amendment application for an Alternate Confidential Statement of Formula for Bayer HealthCare's currently registered product, *CyLence Ultra Insecticide Cattle Ear Tag*, EPA Reg. No. 11556-131. Included with this application are two copies of the draft Alternate Confidential Statement of Formula (CSF) dated 4/03/07.

Bayer HealthCare LLC Animal Health Division 12707 Shawnee Mission Parkway Shawnee Mission, KS 66216-1846

In explanation, Bayer is adding an alternate proprietary inert ingredient component,

These changes are being made by

Amendment as per PR Notice 98-10.

Please contact me at <u>mary.hunt.b@bayer.com</u> or 913-268-2311 if you have any questions.

Respectfully,

BAYER HEALTHCARE LLC ANIMAL HEALTH DIVISION

Mary McKenney Heart

Mary McKinney Hunt Regulatory Specialist

encl: Amendment Application (8570-1) dated 4/03/07

Alternate CSF (8570-4) dated 4/03/07 (2 copies)

Agency letter dated 3/24/06 Agency letter dated 4/13/06 Bayer letter dated 7/18/06



ease read instructions on	reverse before a t	ing form.		Form Appro	OMB No.	2070-00	50. Approval expires 2-28-9
\$EPA	Environmental	nited States Protectio gton, DC 204	•	✓	Registra Amenda Other		OPP Identifier Number
		Applicatio	n for Pesticio	de - Section	n I		
. Company/Product Numbe 11556-131	r			Product Manager e LaRocca (75		3. P	roposed Classification
. Company/Product (Name) CvLence Ultra Cattle Ir			PM# 13				
3ayer HealthCare LL O Box 390 3hawnee Mission, KS	C, Animal Health		(b)(i), m to: EPA F	y product is si	milar or iden	tical in c	n FIFRA Section 3(c)(3) omposition and labeling
		 	Section - I				
Notification - Explain Explanation: Use addition Enclosed for Agency accepts	below. nal page(s) if necessary ance are two (2) copies (r. (For section of the draft Corl change is to a	n I and Section II.) Ifidential Statement of the day and an alternate property.	ietary inert ingred	ated cation. below. April 3, 2007, 1 dient componer	for CyLend	ce Ultra Insecticide Cattle Ear permitted by Amendment per
Material This Product Wil	l Be Packaged In:		Section - II	ı			
Child-Resistant Packaging Yes No * Certification must	Unit Packaging Yes No If "Yes"	No. per	Water Soluble Paragraphic Yes No	No. per	2. Type of	Metal Plastic Glass Paper	
be submitted 3. Location of Net Contents	Unit Packaging wgt. Information Container	container 4. Size(s) Ret	Package wgt	container 5. L	ocation of La		Specify)
6. Manner in Which Label is	Affixed to Product	Lithog Paper Stenci	glued	Other			
1 Contact Brint (Comment	itama dinastrata belave f						o application !
	ments I have made on	Certifica	Title Pesticides Regulation all attachments the	atory Manager	curate and co	Telephon 913-268	6. Date Application Requived
both under applicable 2. Signature	y knowlingly false or relaw. Hirey Hui	F	3. Title Pesticides Regulate 5. Date		• ((Stamped)
Mary McKinney Hunt	Mary McKinney Hunt			April 3, 2007			•••

ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE AMENDMENT Page 1 of 2

CyLence Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131 April 3, 2007

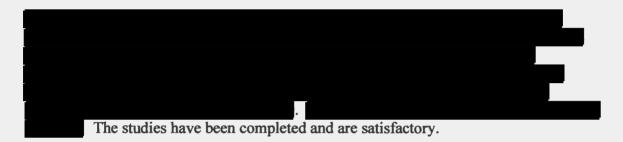
Enclosed for Agency acceptance are two (2) copies of the draft Confidential Statement of Formula, dated April 3, 2007, for CyLence Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131.

The proposed change from the Basic Formulation to the Alternate Formulation follows:



ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE AMENDMENT Page 2 of 2

CyLence Ultra Insecticide Cattle Ear Tag, EPA Reg. No. 11556-131 April 3, 2007



Therefore, we respectfully request an expedited review of the Alternate CSF in order to meet the 2007 campaign production schedule.





Bayer HealthCare Animal Health Division



July 18, 2006

Document Processing Desk (None; Request Letter)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Dr. Bipin Gandhi

Subject:

CyLence Ultra Insecticide Cattle Ear Tag, 11556-131 Co-Ral Plus Insecticide Cattle Ear Tags, 11556-123

use in Bayer's Cattle Ear Tags:

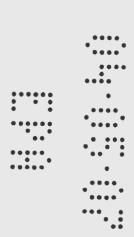
Request for Time Extension

Bayer currently has two cattle ear tags registered – CyLence Ultra Cattle Insecticide, EPA Reg. No. 11556-131 and Co-Ral Plus Insecticide Cattle Ear Tag, EPA Reg. No. 11556-123 – which contain

As Bayer was about

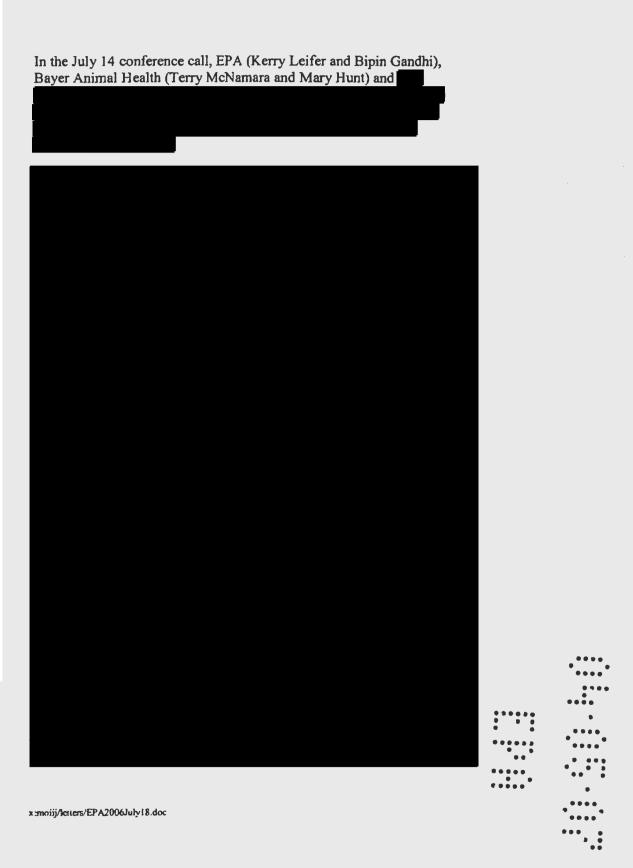
to start production for these two ear tags (the tags are produced in one campaign per year; the campaign about to start will provide tags to be used on cattle in early Spring 2007), Bayer sought guidance from EPA on this matter in a previous June 14, 2006 letter and in a conference call held on July 14, 2006.

x:moiij/letters/EPA2006July18.doc



Animal Health Division 12707 Shawnee Mission Parkway Shawnee, KS 66215

Bayer HealthCare LLC





If you have any questions or comments, please don't hesitate to contact me at (913) 268-2588.

Thank you again for your prompt cooperation and guidance in this matter.

Sincerely,

F. Terry McNamara

Director

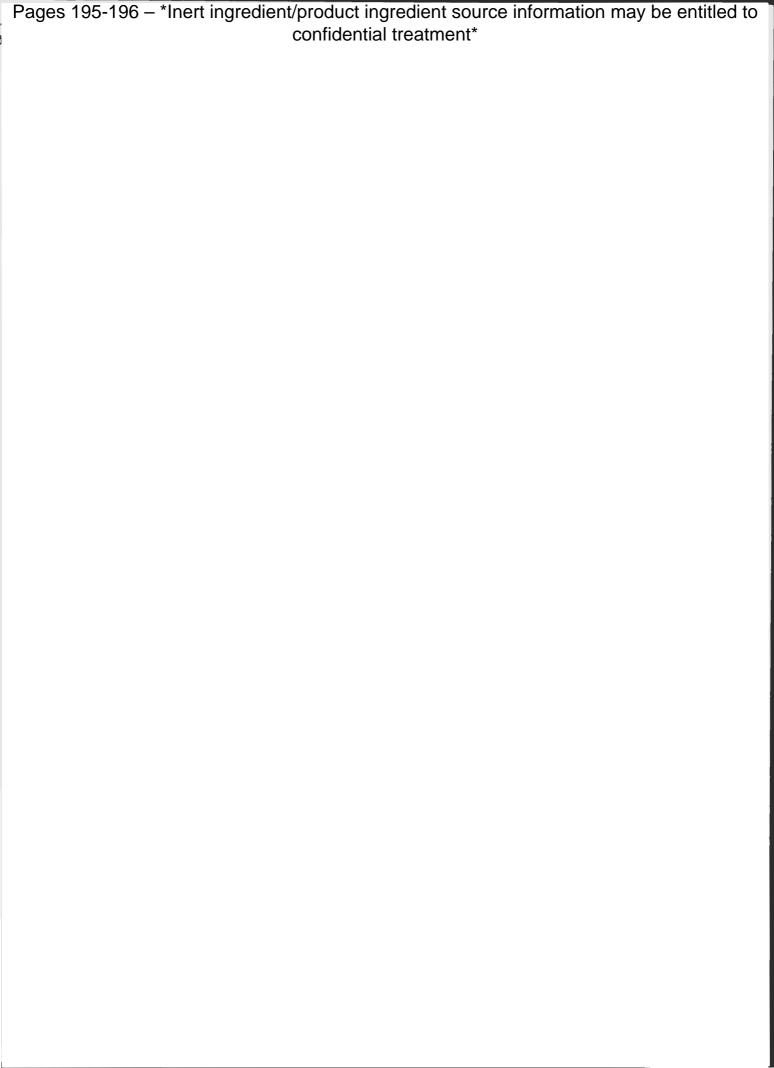
Preclinical Development

y McNamara

FMT/lt

cc: Mr. Kerry Leifer, Inert Team Leader, Registration Division

x:moiij/letters/EPA2006July18.doc





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION. PESTICIDES AND TOXIC SUBSTANCES

07/JUNE/2002

MEMORANDUM

Subject: Name of Pesticide Product: Cutter Ultra Insecticide Cattle Ear Tag

EPA Reg. No. /File Symbol: 11556-131 DP Barcode: D282351 Case No: 069043

PC Code: 067501, 128831

From: Eugenia McAndrew, Biologist

Technical Review Branch

Registration Division (7505C)

To: Susan Stanton, PM Team 03

Insecticide Branch

Registration Division (7505C)

Applicant: Bayer Corporation

Agriculture Division

P.O. Box 390

Shawnee Mission, KS 66201-0390

FORMULATION FROM LABEL:

Active Ingredient(s): % by wt

128831 Cyano (4-fluoro-3-phenoxyphenyl) methyl 3-(2,2-

dichloroethenyl) 2,2-dimethylcyclopropane

067501 Piperonyl butoxide 20

Inert Ingredient(s):

Total:

ACTION REQUESTED: "The originally submitted dermal toxicity 45444601) was reviewed by TRB and found unacceptable. As company was required to submit a new dermal study. The ny attached for your review."

BACKGROUND: Bayer Corporation has submitted an acute dermal toxicity study (MRID 45640701) to support registration of Cutter Ultra Insecticide Cattle Ear Tag, EPA Reg. No.11556-131. A previous dermal toxicity study was classified as unacceptable in a TRB memorandum (McAndrew; D277606; EPA Reg. No. 11556-RGR: 13/SEPT/2001). This new study was conducted at Bayer Corporation Agriculture Division, Toxicology, Stilwell, Kansas. The product was given a conditional registration. The other five acute toxicity studies were waived. Please refer to the 13/SEPT/2001 memorandum for the complete explanation.

RECOMMENDATIONS: The acute dermal toxicity study has been reviewed and is classified as acceptable. The toxicity category for dermal toxicity is category III.

The acute toxicity profile for Cutter Ultra Insecticide Cattle Ear Tag, EPA Reg. No.11556-131, is as follows:

acute oral toxicity	IV	Waived	
acute dermal toxicity	Ш	Acceptable	MRID 45640701
acute inhalation toxicity	IV	Waived	
primary eye irritation	IV	Waived	
primary skin irritation	IV	Waived	
dermal sensitization		Waived	

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

PRODUCT ID #:

011556-00131

PRODUCT NAME:

CUTTER ULTRA CATTLE INSECTICIDE EAR TAG

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD:

CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

First Aid:

If on skin:

- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or g treatment. You may also contact 1-800-xxx-xxx for emergency medical treatment information

DATA EVALUATION RECORD

STUDY TYPE: ACUTE DERMAL TOXICITY TESTING (870.1200 formerly §81-2)

Product Manager: 03 Reviewer: Eugenia McAndrew

TEST MATERIAL PURITY: M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin)

<u>CITATION:</u> Johnson, K.L. (2002); M779 Cattle Ear Tag; acute dermal LD₅₀ in the rat. Bayer Corporation Agriculture Division Toxicology, Stilwell, Kansas. Laboratory Report Number 02-A22-JC. March 19, 2002. MRID 45640701. Unpublished.

SPONSOR: Bayer Corporation, Agriculture Division, P.O. Box 390, Shawnee Mission, KS 66201-0390

EXECUTIVE SUMMARY: In an acute dermal toxicity study, two control groups and one test group of Wistar Hanover (Crl: Wl[Glx/BRL/HAN]GS BR) rats (Age: 11 weeks; Weight: males: 244-280 g; females: 190-215 g; Source: Charles River Laboratories, Inc., Raleigh, NC) were dermally exposed to a single application of M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin; Lot No. M-98-02-M779-99-02-59: light purple tag) for 24 hours. Three groups of six animals/sex were exposed to either 0 mg/kg (collared), 0 mg/kg (uncollared) or 2000 mg/kg (limit dose). The test substance (cattle ear tag) was moistened with 50 μL of deionized water and applied directly to approximately 10% of the body surface area of each test group animal. Body weights were determined prior to dosing and on days 7 and 14. Animals were observed for clinical signs of toxicity and mortality twice daily for five days and then once daily for the remainder of 14 days. Gross necropsies were performed on all animals.

Dermal LD_{50} Males = > 2000 mg/kg (observed); Dermal LD_{50} Females = > 2000 mg/kg (observed)

M779 Cattle Ear Tag is classified as Toxicity Category III based on the observed LD₅₀ values in both sexes.

All animals survived the study. All animals showed body weight gains. Lacrimal and nasal staining and perigenital staining were noted in one control group and in the 2000 mg/kg group. Thinning hair was noted in one treated female and one control female. Alopecia was noted in one treated female. Two treated females exhibited a progression of redness, sore and scabbir at the dose sites. No evidence of systemic toxicity was observed. At necropsy, no gross abnormalities were noted in the treated group. A crusty red zone in the ventral abdominal ar was noted in one control group male.

This study is classified as Acceptable (870.1200) and satisfies the guideline requirement fr acute dermal study in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality stat were provided.

RESULTS:

D	Number of Deaths/Number Tested				
Dosage (mg/kg)	Males	Females	Combined		
0 (collared)	0/6	0/6	0/6		
0 (uncollared)	0/6	0/6	0/6		
2000 (collared)	0/6	0/6	0/6		

OBSERVATIONS: All animals survived the study. All animals showed body weight gains. Lacrimal and nasal staining and perigenital staining were noted in one control group and in the 2000 mg/kg group. Thinning hair was noted in one treated female and one control female. Alopecia was noted in one treated female. Two treated females exhibited a progression of redness, sore and scabbing at the dose sites. No evidence of systemic toxicity was observed.

GROSS NECROPSY: At necropsy, no gross abnormalities were noted in the treated group. A crusty red zone in the ventral abdominal area was noted in one control group male.

ACUTE TOX ONE-LINERS

1. **DP BARCODE**: D282351

2. PC CODE: 067501, 128831 **3. CURRENT DATE:** 07/JUNE/2002

4. TEST MATERIAL: M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin; Lot No. M-98-

02-M779-99-02-59; light purple tag)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute dermal toxicity/rabbit Bayer Corp. Agriculture Division Toxicology 02-A22-JC/3-19-02	45640701	LD ₅₀ > 2000 mg/kg (males females combined)	Ш	А

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION. PESTICIDES AND TOXIC SUBSTANCES

07/JUNE/2002

MEMORANDUM

Subject:

Name of Pesticide Product:

Cutter Ultra Insecticide Cattle Ear Tag

EPA Reg. No. /File Symbol: 11556-131 DP Barcode: Case No:

D282351 069043

PC Code:

067501, 128831

From:

Eugenia McAndrew, Biologist

Technical Review Branch

Registration Division (7505C)

To:

Susan Stanton, PM Team 03

Insecticide Branch

Registration Division (7505C)

Applicant:

Bayer Corporation

Agriculture Division

P.O. Box 390

Shawnee Mission, KS 66201-0390

FORMULATION FROM LABEL:

Active Ingredient(s):

% by wt.

128831

Cyano (4-fluoro-3-phenoxyphenyl) methyl 3-(2,2-

dichloroethenyl) 2,2-dimethylcyclopropane

8

067501

Piperonyl butoxide

20

Inert Ingredient(s):

Total:

ACTION REQUESTED: "The originally submitted dermal toxicity study for this product (MRID) 45444601) was reviewed by TRB and found unacceptable. As a condition of registration, the company was required to submit a new dermal study. The new study (MRID 45640701) is ... attached for your review."

BACKGROUND: Bayer Corporation has submitted an acute dermal toxicity study (MRID 45640701) to support registration of Cutter Ultra Insecticide Cattle Ear Tag, EPA Reg. No.11556-131. A previous dermal toxicity study was classified as unacceptable in a TRB memorandum (McAndrew, D277606; EPA Reg. No. 11556-RGR: 13/SEPT/2001). This new study was conducted at Bayer Corporation Agriculture Division, Toxicology, Stilwell, Kansas. The product was given a conditional registration. The other five acute toxicity studies were waived. Please refer to the 13/SEPT/2001 memorandum for the complete explanation.

RECOMMENDATIONS: The acute dermal toxicity study has been reviewed and is classified as acceptable. The toxicity category for dermal toxicity is category III.

The acute toxicity profile for Cutter Ultra Insecticide Cattle Ear Tag, EPA Reg. No.11556-131, is as follows:

acute oral toxicity	IV	Waived	
acute dermal toxicity	111	Acceptable	MRID 45640701
acute inhalation toxicity	IV	Waived	
primary eye irritation	IV	Waived	
primary skin irritation	IV	Waived	
dermal sensitization		Waived	

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

PRODUCT ID #:

011556-00131

PRODUCT NAME:

CUTTER ULTRA CATTLE INSECTICIDE EAR TAG

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD:

CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

First Aid:

If on skin:

- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

•

DATA EVALUATION RECORD

STUDY TYPE: ACUTE DERMAL TOXICITY TESTING (870.1200 formerly §81-2)

Product Manager: 03 Reviewer: Eugenia McAndrew

TEST MATERIAL PURITY: M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin)

<u>CITATION:</u> Johnson, K.L. (2002); M779 Cattle Ear Tag; acute dermal LD₅₀ in the rat. Bayer Corporation Agriculture Division Toxicology, Stilwell, Kansas. Laboratory Report Number 02-A22-JC. March 19, 2002. MRID 45640701. Unpublished.

SPONSOR: Bayer Corporation, Agriculture Division, P.O. Box 390, Shawnee Mission, KS 66201-0390

EXECUTIVE SUMMARY: In an acute dermal toxicity study, two control groups and one test group of Wistar Hanover (Crl: WI[Glx/BRL/HAN]GS BR) rats (Age: 11 weeks; Weight: males: 244-280 g; females: 190-215 g; Source: Charles River Laboratories, Inc., Raleigh, NC) were dermally exposed to a single application of M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin; Lot No. M-98-02-M779-99-02-59: light purple tag) for 24 hours. Three groups of six animals/sex were exposed to either 0 mg/kg (collared), 0 mg/kg (uncollared) or 2000 mg/kg (limit dose). The test substance (cattle ear tag) was moistened with 50 μL of deionized water and applied directly to approximately 10% of the body surface area of each test group animal. Body weights were determined prior to dosing and on days 7 and 14. Animals were observed for clinical signs of toxicity and mortality twice daily for five days and then once daily for the remainder of 14 days. Gross necropsies were performed on all animals.

Dermal LD₅₀ Males = > 2000 mg/kg (observed); Dermal LD₅₀ Females = > 2000 mg/kg (observed)

M779 Cattle Ear Tag is classified as Toxicity Category III based on the observed LD_{50} values in both sexes.

All animals survived the study. All animals showed body weight gains. Lacrimal and nasal staining and perigenital staining were noted in one control group and in the 2000 mg/kg group. Thinning hair was noted in one treated female and one control female. Alopecia was noted in one treated female. Two treated females exhibited a progression of redness, sore and scabbing at the dose sites. No evidence of systemic toxicity was observed. At necropsy, no gross abnormalities were noted in the treated group. A crusty red zone in the ventral abdominal area was noted in one control group male.

This study is classified as Acceptable (870.1200) and satisfies the guideline requirement for an acute dermal study in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS:

Bassa (marilia)	Number of Deaths/Number Tested			
Dosage (mg/kg)	Males	Females	Combined	
0 (collared)	0/6	0/6	0/6	
0 (uncollared)	0/6	0/6	0/6	
2000 (collared)	0/6	0/6	0/6	

OBSERVATIONS: All animals survived the study. All animals showed body weight gains. Lacrimal and nasal staining and perigenital staining were noted in one control group and in the 2000 mg/kg group. Thinning hair was noted in one treated female and one control female. Alopecia was noted in one treated female. Two treated females exhibited a progression of redness, sore and scabbing at the dose sites. No evidence of systemic toxicity was observed.

GROSS NECROPSY: At necropsy, no gross abnormalities were noted in the treated group. A crusty red zone in the ventral abdominal area was noted in one control group male.

ACUTE TOX ONE-LINERS

1. **DP BARCODE**: D282351

PC CODE: 067501, 128831
 CURRENT DATE: 07/JUNE/2002

4. TEST MATERIAL: M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin; Lot No. M-98-

02-M779-99-02-59; light purple tag)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute dermal toxicity/rabbit Bayer Corp. Agriculture Division Toxicology 02-A22-JC/3-19-02	45640701	LD ₅₀ > 2000 mg/kg (males females combined)	111	Α

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

07/JUNE/2002

MEMORANDUM

Subject:

Name of Pesticide Product:

Cutter Ultra Insecticide Cattle Ear Tag

EPA Reg. No. /File Symbol: 11556-131 DP Barcode:

D282351

Case No:

069043

PC Code:

067501, 128831

From:

Eugenia McAndrew, Biologist

Technical Review Branch

Registration Division (7505C)

To:

Susan Stanton, PM Team 03

Insecticide Branch

Registration Division (7505C)

Applicant:

Bayer Corporation

Agriculture Division

P.O. Box 390

Shawnee Mission, KS 66201-0390

FORMULATION FROM LABEL:

Active Ingredient(s):

% by wt.

128831

Cyano (4-fluoro-3-phenoxyphenyl) methyl 3-(2,2dichloroethenyl) 2,2-dimethylcyclopropane

8

067501

Piperonyl butoxide

20

Inert Ingredient(s):

Total:

ACTION REQUESTED: "The originally submitted dermal toxicity study for this product (MRID 45444601) was reviewed by TRB and found unacceptable. As a condition of registration, the company was required to submit a new dermal study. The new study (MRID 45640701) is ••• attached for your review."

BACKGROUND: Bayer Corporation has submitted an acute dermal toxicity study (MRID 45640701) to support registration of Cutter Ultra Insecticide Cattle Ear Tag. EPA Reg. No.11556-131. A previous dermal toxicity study was classified as unacceptable in a TRB memorandum (McAndrew; D277606; EPA Reg. No. 11556-RGR: 13/SEPT/2001). This new study was conducted at Bayer Corporation Agriculture Division, Toxicology, Stilwell, Kansas. The product was given a conditional registration. The other five acute toxicity studies were waived. Please refer to the 13/SEPT/2001 memorandum for the complete explanation.

RECOMMENDATIONS: The acute dermal toxicity study has been reviewed and is classified as acceptable. The toxicity category for dermal toxicity is category III.

The acute toxicity profile for Cutter Ultra Insecticide Cattle Ear Tag, EPA Reg. No.11556-131, is as follows:

acute oral toxicity	IV	Waived	
acute dermal toxicity	111	Acceptable	MRID 45640701
acute inhalation toxicity	IV	Waived	
primary eye irritation	IV	Waived	
primary skin irritation	IV	Waived	
dermal sensitization		Waived	

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

PRODUCT ID #:

011556-00131

PRODUCT NAME:

CUTTER ULTRA CATTLE INSECTICIDE EAR TAG

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD:

CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

First Aid:

If on skin:

- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

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DATA EVALUATION RECORD

STUDY TYPE: ACUTE DERMAL TOXICITY TESTING (870.1200 formerly §81-2)

Product Manager: 03 Reviewer: Eugenia McAndrew

TEST MATERIAL PURITY: M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin)

<u>CITATION:</u> Johnson, K.L. (2002); M779 Cattle Ear Tag; acute dermal LD₅₀ in the rat. Bayer Corporation Agriculture Division Toxicology, Stilwell, Kansas. Laboratory Report Number 02-A22-JC. March 19, 2002. MRID 45640701. Unpublished.

<u>SPONSOR:</u> Bayer Corporation, Agriculture Division, P.O. Box 390, Shawnee Mission, KS 66201-0390

EXECUTIVE SUMMARY: In an acute dermal toxicity study, two control groups and one test group of Wistar Hanover (Crl: WI[Glx/BRL/HAN]GS BR) rats (Age: 11 weeks; Weight: males: 244-280 g; females: 190-215 g; Source: Charles River Laboratories, Inc., Raleigh, NC) were dermally exposed to a single application of M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin; Lot No. M-98-02-M779-99-02-59: light purple tag) for 24 hours. Three groups of six animals/sex were exposed to either 0 mg/kg (collared), 0 mg/kg (uncollared) or 2000 mg/kg (limit dose). The test substance (cattle ear tag) was moistened with 50 μ L of deionized water and applied directly to approximately 10% of the body surface area of each test group animal. Body weights were determined prior to dosing and on days 7 and 14. Animals were observed for clinical signs of toxicity and mortality twice daily for five days and then once daily for the remainder of 14 days. Gross necropsies were performed on all animals.

Dermal LD_{50} Males = > 2000 mg/kg (observed); Dermal LD_{50} Females = > 2000 mg/kg (observed)

M779 Cattle Ear Tag is classified as Toxicity Category III based on the observed LD_{50} values in both sexes.

All animals survived the study. All animals showed body weight gains. Lacrimal and nasal staining and perigenital staining were noted in one control group and in the 2000 mg/kg group. Thinning hair was noted in one treated female and one control female. Alopecia was noted in one treated female. Two treated females exhibited a progression of redness, sore and scabbing at the dose sites. No evidence of systemic toxicity was observed. At necropsy, no gross***. abnormalities were noted in the treated group. A crusty red zone in the ventral abdominal area was noted in one control group male.

This study is classified as Acceptable (870.1200) and satisfies the guideline requirement for an acute dermal study in the rat.

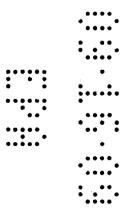
<u>COMPLIANCE:</u> Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS:

	Number of Deaths/Number Tested			
Dosage (mg/kg)	Males	Females	Combined	
0 (collared)	0/6	0/6	0/6	
0 (uncollared)	0/6	0/6	0/6	
2000 (collared)	0/6	0/6	0/6	

OBSERVATIONS: All animals survived the study. All animals showed body weight gains. Lacrimal and nasal staining and perigenital staining were noted in one control group and in the 2000 mg/kg group. Thinning hair was noted in one treated female and one control female. Alopecia was noted in one treated female. Two treated females exhibited a progression of redness, sore and scabbing at the dose sites. No evidence of systemic toxicity was observed.

<u>GROSS NECROPSY:</u> At necropsy, no gross abnormalities were noted in the treated group. A crusty red zone in the ventral abdominal area was noted in one control group male.



ACUTE TOX ONE-LINERS

1. DP BARCODE: D282351

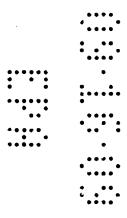
2. PC CODE: 067501, 128831 **3. CURRENT DATE:** 07/JUNE/2002

4. TEST MATERIAL: M779 Cattle Ear Tag (20% PBO and 8% beta cyfluthrin; Lot No. M-98-

02-M779-99-02-59; light purple tag)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute dermal toxicity/rabbit Bayer Corp. Agriculture Division Toxicology 02-A22-JC/3-19-02	45640701	LD ₅₀ > 2000 mg/kg (males females combined)	III	Α

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

13/SEPT/2001

MEMORANDUM

Subject:

Name of Pesticide Product: Cutter Ultra Cattle Insecticide Ear Tag

EPA Reg. No. /File Symbol: 11556-RGR

DP Barcode:

D277606

Case No:

069043

PC Code:

067501, 128831

From:

Eugenia McAndrew, Biologist & M

Technical Review Branch

Registration Division (7505C)

To:

Tracy Keigwin, PM Team 03

Insecticide Branch

Registration Division (7505C)

Applicant:

Bayer Corporation

Agriculture Division, Animal Health

P.O. Box 390

Shawnee Mission, KS 66201-0390

FORMULATION FROM LABEL:

Activ	e Ingredient(s):	% by wt.	
128831	Cyano (4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl) 2,2-dimethylcyclopropane		•***•
	carboxylate	8	• • • • • • • • • • • • • • • • • • • •
067501	Piperonyl butoxide	20	
Inert	Ingredient(s): Total:	<u>72</u> 100%	•

ACTION REQUESTED: Please review dermal toxicity study (MRID # 454446-01) submitted to support registration of Cutter Ultra Cattle Insecticide Ear Tag, EPA File Symbol 11556-RGR.

BACKGROUND: Bayer Corporation has applied for registration of Cutter Ultra Cattle Insecticide Ear Tag, EPA File Symbol 11556-RGR. This product is a cattle ear tag constructed of a plastic impregnated with two active ingredients for use on beef and non-lactating dairy cattle to control face flies, horn flies, gulf coast ticks and spinose ear ticks for up to five months. TRB has addressed the acute toxicity data requirements for this product in memos dated October 26, 2000 and November 6, 2000, in a letter dated January 9, 2001 and in a telephone conversation with the registrant on January 30, 2001. TRB is requiring an acute dermal toxicity study and asked the registrant to provide a rationale for waivers for the other five acute toxicity studies.

The registrant has now submitted an acute dermal toxicity study (MRID # 454446-01). The study was conducted at Bayer Corporation, Agriculture Division, Toxicology, Stilwell, Kansas. The registrant has also submitted the request for waivers for the acute oral, acute inhalation, primary eye irritation, primary skin irritation and dermal sensitization studies.

RECOMMENDATIONS: Waivers may be granted for the acute oral, acute inhalation, primary eye irritation, primary skin irritation and dermal sensitization studies.

The acute dermal toxicity study is classified as unacceptable. TRB has serious concerns that the health of the animals used in the study may have been compromised as evidenced by the unexplained death of one animal in the treated group and by the number of clinical signs such as lacrimal staining, red or brown discharge in the nose and/or eyes, thinning hair around forelimbs and/or eyes, swelling around the neck and thinness seen in the control animals. TRB has reviewed the clarifications on this study submitted by Bayer in a memo dated September 7, 2001 and has concluded that the study is unacceptable because of these preceding discrepancies.

The tentative acute toxicity profile for Cutter Ultra Cattle Insecticide Ear Tag, EPA File Symbol 11556-RGR, is as follows:

acute oral toxicity	١V	Waived	
acute dermal toxicity	111	Unacceptable	MRID 454446-01
acute inhalation toxicity	IV	Waived	
primary eye irritation	IV	Waived	
primary skin irritation	IV	Waived	
dermal sensitization	IV	Waived	
			••••

TRB has assigned a Toxicity Category of III for the acute dermal toxicity study. TRB has no objection to a conditional registration of EPA File Symbol 11556-RGR (per John Redden,:Acute Tox Team Leader and Acting-Branch Chief). The acute dermal toxicity study must be repeated.

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LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

ID #: 011556-00131 Cutter Ultra Cattle Insecticide Ear Tag

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.





Agriculture Division

June 22, 2000

Mr. George LaRocca
Registration Division (H7504C)
Office of Pesticide Programs
U.S. ENVIRONMENTAL PROTECTION AGENCY
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Crop Protection Products

Bayer Corporation 8400 Hawthorn Road P.O. Box 4913 Kansas City, MO 64120-0013 Phone: 816 242-2000

SUBJECT: Use of Bayer Corporation Research and Test Data

Dear Mr. LaRocca:

Bayer Corporation, Agriculture Division, hereby authorizes the Agency to refer to the Bayer research and test data for Beta-Cyfluthrin, in support of the registration of products containing the active ingredient **Beta-Cyfluthrin**, submitted by **Bayer Animal Health**, Company Number 11556.

Cutter Ultra Insecticide Ear Tag 11556-XXXX RGR

This authorization is granted only to the applicant named above for the product registrations described. This authorization may not be transferred by the applicant named above in any manner whatsoever without the express prior consent of Bayer Corporation. All Information contained in our confidential ingredients statement or otherwise claimed as being confidential or proprietary may not be released to the applicant without the express prior consent of Bayer Corporation.

Bayer Corporation hereby waives the 30-day notification period prior to registration of this application as provided for in 40 CFR 152, Subpart E, Section 152.116(c).

Sincerely,

Charles W. Boyd

Senior Registration Scientist

Research and Development

Charles W. Bayo

/cwb

attachment

CC:

Gregg Gadliano

P.O. Box 390

Shawnee Mission, Kansas 66210